IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
DIANNE M. BELLEW, Plaintiff,	
-vs-	No. 13-CV-22473
ETHICON, INC., ET AL., Defendants.	

VIDEOTAPED DEPOSITION OF

DENISE M. ELSER, M.D.

September 16, 2014

Chicago, Illinois

The videotaped deposition of DENISE M. ELSER, M.D., called by the Plaintiff for examination, taken pursuant to the Federal Rules of Civil Procedure of the United States District Courts pertaining to the taking of depositions, taken before CORINNE T. MARUT, C.S.R. No. 84-1968, Registered Professional Reporter and a Certified Shorthand Reporter of the State of Illinois, at the Park Hyatt Chicago, 800 North Michigan Avenue, Chicago, Illinois, on September 16, 2014, commencing at 10:37 a.m.

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EXHIBITS

(WHEREUPON, a certain document was marked Elser Deposition Exhibit No. 1, Expert Report of Denise Elser, M.D., for identification.)

THE VIDEOGRAPHER: We are now on the record. My name is Milo Savich. I am a videographer for Golkow Technologies.

Today's date is September 16, 2014 and the time is 10:37 a.m.

This video deposition is being held in Chicago, Illinois in the matter of Dianne M. Bellew vs. Ethicon, Inc. et al., for the United States District Court, Southern District of West Virginia at Charleston.

The deponent is Dr. Denise Elser.

Will counsel please identify themselves for the record.

MR. COMBS: Phil Combs and Paul Rosenblatt on behalf of the Defendants.

MR. SLATER: Adam Slater for the Plaintiff.

THE VIDEOGRAPHER: The Court Reporter is Corinne Marut who will now swear in the witness and we can proceed.

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(WHEREUPON, the witness was duly sworn.)
DENISE M. ELSER, M.D.,
called as a witness herein, having been first duly sworn, was examined and testified as follows:
EXAMINATION
BY MR. SLATER:
Q. Good morning, Dr. Elser.
A. Good morning.
Q. I'm not sure if I heard you. Can you just say something. Hello?
A. Hello, good morning.
Q. Okay. I hear you. Okay.
Dr. Elser, my name is Adam Slater. I'm going to take your deposition now in the case. You understand that's why we're here today?
A. Yes.
Q. I'm going to ask you questions and since you're under oath, you understand you must tell the truth, correct?
A. Yes.
Q. If I ask you a question that doesn't make sense to you for some reason, just let me know and I'll rephrase the question. Okay?
A. Okay.

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Q. Let's mark as Exhibit -- I think we already did -- Elser 1, the report. Do we have that there?
A. I have Exhibit 1. Elser 1.
Q. Dr. Elser, in front of you is what we've marked as Exhibit Elser 1. Can you tell me what that is?
A. It's the expert report that I prepared in relation to this case.
Q. Do you know what date it is that you completed this report?
A. Give me a second. I'm just looking for the signature page, which I did not date. No, I don't. I believe it was three or four weeks ago.
Q. That would be sometime in the middle of August?
A. Correct.
Q. About?
A. That would be -- that would be my estimate, correct.
Q. Does this report contain each of the opinions that you've reached in this case?
A. To date, yes.
Q. In this report you go through various facts and you discuss various facts. Did you

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discuss those facts that you felt were most important to you in drawing the opinions that are found in the report?
A. Yes.
Q. I'm sorry. What was the answer?
A. Yes.
Q. Okay. The report itself appears to go to page 39 and then you have a list of literature that begins after the report. Is that correct?
A. So, the literature list starts on page 39.
Q. The list of literature that starts on page 39 and goes through page 44, what is that list?
A. These were references that I specifically cited in the report.
Q. Is that the collection of literature that you relied on in forming your opinions in this case?
A. No, those were just ones from which I took specific citations.
Q. In terms of your decision making in writing your report, why did you cite those articles in your report?
A. They may have contained certain figures

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or facts that I wanted to stress, but those are not the only articles I've read on prolapse that are used to form my opinions on treatment of prolapse or of this patient.
Q. To the extent you directly relied on an article or a piece of literature in your report, the only way for me to know that by reading your report would be to read the report and see the citation, correct?
A. If I specifically quoted a figure or a fact out of a report, then I cited it on these pages here. Can you -- do you want to rephrase your question?
Q. No.
A. Okay.
Q. If we go to Attachment A to your report, it's a curriculum vitae. Is that your current curriculum vitae?
A. Yes.
Q. Within your curriculum vitae is a list of publications. Do any of the publications directly relate to the prolapse -- Prolift?
MR. COMBS: Object to form.
MR. SLATER: I'll reask the question.
BY MR. SLATER:

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Q. The list of publications in your curriculum vitae, do any of them specifically address the Prolift?
A. No.
Q. Do any of your publications specifically address the TVM technique for the treatment of prolapse?
A. No.
Q. Would you agree with me that the Prolift is an augmentation -- or rephrase.
Would you agree with me that the Prolift is an alternative surgical procedure for the treatment of prolapse as compared to other techniques that are available to physicians?
A. Yes.
Q. You said yes, correct?
A. Yes.
Q. Do any of your publications address complications from the use of mesh to treat prolapse?
A. There was the abstract from IUGA where the lead author was Furlong where we reported on some complications after vaginal mesh surgery, not specifically the Prolift.
Q. Is that listed on your list there?

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A. I believe it is. I'll check it.
Q. Can you tell me where it is. I might just be overlooking it.
A. Page 40.
Q. Page 40?
A. On my report.
Q. Let me look. Let me go back.
On page 40 of your report, which is your list of references, there is an article -- rephrase.
On the list of literature at the end of your report on page 40 there is a reference to Furlong, F-u-r-l-o-n-g, Elser and Moen. What is that?
A. It's an abstract that was a poster at the SGS meeting in 2009. We reported on complications related to biologic graft or synthetic mesh used in vaginal surgery for prolapse.
Q. At the SGS meeting in New Orleans in 2009 you presented a poster presentation, correct?
A. It was a poster.
Q. And that means the poster was presented, you did not actually have a speaking or a presentation role at that meeting, correct?

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A. Correct.
Q. And this poster was detailing complications that had been seen by yourself and your co-authors with the use of grafts and mesh augmentation in the treatment of prolapse?
A. Yes.
Q. Did that include complications seen from Prolift?
A. The abstract does not specify which products were used during this time period, but I imagine some are Prolift.
Q. As you sit here now do you know whether or not any of these complications related to the use of the Prolift?
A. It was the time period when our practice did use Prolift. So, I -- I would say yeah, some of them were Prolift. But how many, I can't tell you. We just separated by biologic versus synthetic.
Q. And just so I understand some vocabulary. This was a poster presentation, the Furlong presentation. That's not an abstract. That's a poster. There's a difference, correct?
A. It was a published abstract and it was a poster.

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Q. When you say there was a published poster, what was there some sort of a booklet of presentations that was circulated in connection with that meeting?
A. Well, the Journal of Pelvic Medicine and Surgery has a list of published abstracts that were accepted for the meeting.
Q. So, there was a poster presentation. Is the abstract exactly the same as the poster?
A. I can't say exactly. Sometimes there is an additional picture on posters. I don't remember specifically for this one. But no additional information.
Q. Is the Furlong, Elser, Moen presentation on complications related to graft or mesh augmentation listed anywhere in your curriculum vitae?
A. No, I don't see it.
Q. Why didn't you list this poster presentation which you've told me also was an abstract, why isn't that listed in your curriculum vitae?
A. Oversight.
Q. Are there any other abstracts, presentations or publications of yours that relate

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to the use of mesh to treat prolapse that are not listed in your curriculum vitae?
A. Not that I'm aware of.
Q. How about with regard to the treatment of stress incontinence?
A. Not that I'm aware of.
Q. Was there ever a time when this presentation was listed in your CV and that it was deleted for some reason?
A. No. I think it's more a matter of recordkeeping that I didn't always write down my abstracts.
Q. If I request counsel to get that from you, would you be able to provide to me a copy of the poster and the abstract?
MR. COMBS: Yeah, Adam, we'll be glad to. It's in the body of her report, the information from that. But, yes, we will provide you a copy of that abstract.
MR. SLATER: And the poster as well, okay?
MR. COMBS: If, if we have a copy of the poster we'll provide that to you. I don't personally have a copy of the poster, but I can tell you that I can get you a copy of the abstract. If we have the poster, we'll give you the poster

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too.
BY MR. SLATER:
Q. Dr. Elser, do you have a copy of the poster that was presented?
A. I do not have a copy.
Q. Do you know if Dr. Furlong or Dr. Moen has it?
A. Dr. Moen would not have it and I don't know if Dr. Furlong has it.
Q. I will just ask that an effort be made to identify it and produce it.
Did you utilize Gynemesh PS in your medical practice?
A. Yes.
Q. During what time period?
A. It would have been prior to 2005.
Q. Can you tell me more specific than that when you used it, for how long?
A. No, I don't recall.
Q. When you used Gynemesh PS prior to 2005, did you just use that where you would cut portions of it to help you in treating prolapse where you were using native tissue repair?
A. Well, I would use it for a mesh augmented repair where we cut our own mesh to place

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vaginally or for a sacrocolpopexy potentially.
Q. Why did you stop using Gynemesh PS as sold at that product?
A. For sacrocolpopexy I wanted a longer piece of mesh, and for the vaginal mesh procedures we transitioned into kits when they became available.
Q. When did you first begin to use a kit for the treatment of prolapse?
A. I don't recall exactly, but it would have been around 2005, 2006.
Q. Which kit did you first use?
A. Well, I had -- I had actually used the Posterior IVS initially before Prolift was available.
Q. Are you saying you first used the Posterior IVS and then you went to the Prolift?
A. Correct.
Q. Other than the Posterior IVS and the Prolift have you used any other kits for the treatment of prolapse?
A. I have. I had used the Apogee/Perigee. I've used the Elevate. I have used the Pinnacle.
Q. I'd like to get the chronology of your use of the kits. You started with the

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Posterior IVS. When did you use that? During what time period?
A. I don't -- I don't have the years. I don't have records available to look at to tell you what years I used it.
Q. Well, you said earlier you believed it was about 2005, 2006 when you began to use the Posterior IVS?
A. When I began to use Prolift. So, let me clarify that. Posterior IVS, I would have to go back and look when it was available, when I had used it.
Q. The first kit that you used for the treatment of prolapse was the Posterior IVS, correct?
A. Correct.
Q. And then sometime around 2005, 2006 you began to use the Prolift?
A. Right.
Q. At the time you began to use the Prolift had you used any other kits besides the Posterior IVS?
A. I don't recall the chronology of whether I had used Perigee/Apogee, you know, around the same time I started using Prolift.

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Q. For how long did you use the Apogee/Perigee kits?
A. Maybe a year.
Q. How many times would you estimate you used those total?
A. I'm going to have to make estimates here because I don't have records and haven't looked at this. I would say under a dozen for the Perigee/Apogee.
Q. You began to use the Prolift in 2005 or 2006. When did you stop using the Prolift?
A. When it was no longer available.
Q. And when was it that it ceased to be available to you?
A. Oh, I don't recall the exact date.
Q. How many times did you use the Prolift to treat prolapse?
A. Again, this is going to be an estimate. Over 100.
Q. During the time that you were using the Prolift, did you also continue to do native tissue repairs with suture?
A. Yes.
Q. Did you view the native tissue repairs with suture as an alternative to Prolift and vice

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versa meaning that in any patient you would look at risks/benefits and then consult with the patient and determine which procedure would be done for that patient if either one was appropriate for that condition?
A. That's right. It would be based on patient selection.
Q. You also have performed abdominal sacrocolpopexy, correct?
A. Yes.
Q. Have you been performing that procedure since at least 2005 up until the present?
A. Performed my first one before 1995.
Q. In terms of alternative treatments for a patient, abdominal sacrocolpopexy would be one of the alternatives if in fact there was a prolapse in that part of the pelvis that would be appropriate for that treatment?
A. Right. It's one of the -- one of the surgeries we have available to treat prolapse.
Q. What meshes have you used for abdominal sacrocolpopexy?
A. I have used Gore-Tex graft, which can't -- is not really a mesh. I have used Marlex, Mersilene, Gynemesh, IntePro and Restorelle, Alyte

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and probably others that I don't remember.
Q. What do you currently use?
A. Most commonly the Restorelle.
Q. In terms of your use of the Prolift, did there come a time when the frequency of your use of the Prolift began to diminish?
A. Yes.
Q. When was that?
A. Most notably, vaginal mesh in general would be after the 2011 FDA notification came out and patients were very wary of vaginal mesh.
But before that we were -- my partner and I were going to be involved in a Pinnacle study and we were using Pinnacle more to prepare for the study.
Q. When did you use the Pinnacle, during what time period?
A. I don't recall the years. It would -- it was from whenever it became available until 2011.
Q. Do you have an estimate of when the Pinnacle became available?
A. I don't recall.
Q. Would it be around 2007 or 2008?
A. I would be --

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Q. Does that sound correct?
A. I would be guessing. That sounds around the right time.
Q. When you began to use the Pinnacle, you -- did you stop using the Prolift altogether or just significantly decrease your use of the Prolift?
A. Decreased my use.
Q. And why did you begin to use the Pinnacle rather than the Prolift?
A. I wanted to be familiar with the product as we were going to enroll patients in a clinical study.
Q. When that point came were you offering the Prolift and the Pinnacle as options to your patients or were you telling them that if they want to have a kit done, you were offering them the Pinnacle at that point?
A. I would have talked to the patient about vaginal mesh repair and then I chose the kit typically.
Q. So, when you consented patients with mesh repair kits, you didn't speak to them about the specific manufacturer and compared the different kits that were available that you were

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able to use. You just talked about vaginal mesh in general and then you chose the kit. Is that correct?
A. Typically.
Q. Were there qualitative differences from your perspective between the Pinnacle and the Prolift that would make one or the other more appropriate for certain patients?
A. No.
Q. How many Pinnacle procedures would you estimate you did?
A. Again, a guess. Around 40.
Q. When did you stop using the Pinnacle?
A. I don't think I've used it in about three years.
Q. Sometime in 2011?
A. That sounds right.
Q. When did you begin to use the Elevate?
A. I think around 2011.
Q. Why did you begin to use the Elevate?
A. I was interested in the way it was attached and I liked the mesh it had as well and that's the product I'm currently using when I perform vaginally mesh-augmented procedures.
Q. Are there any significant differences

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between the Elevate and the Prolift?
A. The Elevate has attachments that are directed from the vaginal incision into the sacrospinous ligament and into the white line and there is not a trocar pass through the obturator membrane from the outside.
Q. One significant difference between the Elevate and the Prolift is that the Elevate does not have trocar passes, correct?
A. Right. From the outside in. It has trocars that you pass little mesh arms with, but it doesn't have the trocar pass from the outside in through the obturator membrane.
Q. The mesh for the Elevate is different from the Prolift mesh, correct?
A. They're both polypropylene meshes. There may be some differences.
Q. Well, wouldn't it be true that from your perspective there is a difference, for example, in the weight and the flexibility of the Elevate mesh versus the Prolift mesh?
A. I have not compared the two side by side in a while or read about the differences recently. So, I would have to look at both of them.
Q. When you began to use the Elevate in

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2011, at that point did you cease using the Prolift?
A. It was close to the same time, but it was not exclusive that I necessarily went to one and abandoned the other when both were available.
Q. At the point when you began to use the Elevate, were the vast majority of procedures that you did where a mesh kit was involved, was that done with the Elevate at that point going forward?
A. Yes.
Q. From the point when you began to use the Elevate, how many Prolift procedures did you use -- rephrase that.
From the point you began to use the Elevate, how many Prolift procedures did you do on a going-forward basis?
A. I don't know that number.
Q. It would be less than two or three, wouldn't it?
A. I don't know.
Q. It would be less than five, right?
A. I don't recall a number. It was not a set decision to abandon one product and move to the other. So, I might have used either one depending on what was available in the OR.

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Q. The fact that there were no external trocar passes with the Elevate, you saw that as a benefit from a safety perspective as compared to the Prolift, correct?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. I saw it as potential benefit, but I -- it did not determine it was a safer product.
MR. SLATER: Move to strike from "but" forward.
BY MR. SLATER:
Q. In your patients in evaluating the risk/benefit profile, is it true that you saw the Elevate with no external trocar passes as offering a safety advantage compared to the Prolift which had the external trocar passes?
A. Yes, if I can explain. The -- the trocar pass, the risk was a potential for injury to the bladder during the procedure or a risk of injury to a blood vessel during the passage.
In my experience I experienced one bladder injury using a Prolift and never had a hemorrhage or hitting a blood vessel, so it was not a major reason to make a switch necessarily. It was a potential decreasing risk of a very rare

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complication.
MR. SLATER: Move to strike after "yes."
BY MR. SLATER:
Q. One of the risks with the external trocar passes with the Prolift is that nerves will be damaged, correct?
A. Any time you have a surgery there is a risk that nerve will be damaged.
Q. With the external trocar passes with the Prolift, one of the risks is that the trocar will enter the body and damage nerves, correct?
A. Can you be more specific? Are you asking about a specific nerve or any kind of nerve?
Q. I'm right now asking about nerves in general. That's one of the risks, right?
A. That's a risk of any surgery.
MR. SLATER: Move to strike.
BY MR. SLATER:
Q. I know that -- I was told at the start of the deposition, Dr. Elser, that there is a hard stop time. I've been given a limited time to take the deposition. So I'd appreciate if I ask you a direct question, if we just stick with that question, that way we can move more efficiently.
MR. COMBS: Okay. And if we're going to be

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putting statements on the record, obviously we sat here for more than 45 minutes waiting on you to be ready to start the deposition. We are ready to go forward. Let's just go forward.
MR. SLATER: Mr. Combs, I was a half hour late because on the Interstate 287 south, which I drive to my office each day, there was a fatal accident. So, I was diverted around it and saw a body underneath a white sheet with emergency vehicles around it, which caused me to be 30 minutes late. So, I apologize for that, but that was something beyond my control.
MR. COMBS: Well, let's not act like that the reason that if the deposition isn't concluded by 5:00 is going to be because Dr. Elser isn't answering your questions. She is answering your questions.
MR. SLATER: I'm sorry. I'm not acting like anything. The last question was not responsive. I move to strike. Witnesses who are expert should answer directly. That's my understanding.
MR. COMBS: Well, she is answering your questions.
MR. SLATER: Okay. Thank you very much.
BY MR. SLATER:

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Q. Dr. Elser, with the external trocar passes from the Prolift, one of the risks is that the trocar can injure a nerve during the procedure, correct?
A. Yes. There is a risk a trocar can injure a nerve and there's a risk a scalpel can injure a nerve. There is a risk a scissor can injure a nerve.
MR. SLATER: Move to strike from "and" forward.
BY MR. SLATER:
Q. Did you ever tell anybody that you thought the Elevate had certain safety advantages with regard -- as compared to the Prolift?
MR. COMBS: Object to form.
BY THE WITNESS:
A. I don't recall that.
BY MR. SLATER:
Q. You wouldn't deny it if somebody were to say that, you wouldn't be surprised if you said that, would you?
A. I would be surprised.
Q. Let's go back to your CV -- I mean your report. Rephrase.
Let's go to Attachment B to your report.

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This is a list, "Reliance List in Addition to Materials Referenced in Report." That's what it's titled, correct?
A. Correct.
Q. The first portion of this list is a list of articles and literature, correct?
A. Correct.
Q. Did you compile this list or was this compiled for you?
A. This was compiled for me.
Q. This list was compiled for you by counsel, correct?
A. Yes.
Q. Is that correct?
A. Yes.
Q. Throughout your report and your literature list and the list of literature listed are articles relating to midurethral slings and the TVT products, correct?
A. Correct.
Q. In forming your opinions, did you rely on midurethral slings and the TVT to form any of your opinions regarding safety and efficacy of the Prolift?
A. I primarily referred -- I relied on

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articles specifically related to prolapse and my experience in treating prolapse. But slings did give us experience with vaginal mesh.
Q. Here's what I want to know: In forming your opinions in this case, are you relying on literature or studies with regard to the treatment of stress urinary incontinence with midurethral slings like the TVT products?
MR. COMBS: Asked and answered.
BY THE WITNESS:
A. Are you -- can I ask a clarification?
BY MR. SLATER:
Q. Yes.
A. Are you asking if I'm going to pull data from a sling article and say it relates to problems with prolapse repair?
Q. Let's start with this. Are you relying on any data or findings in any of the TVT or midurethral sling literature in order to form your opinions in this case regarding the Prolift?
A. I don't think I am specifically.
Q. Nothing you can point to now, correct?
A. Can you say that again. I didn't hear it.
Q. Nothing that you could point to now,

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right?
A. Correct.
Q. Did you -- well, rephrase that. Let me withdraw that.
If there was an article that you thought was important to you in forming your opinions, would it be fair to say it would be in the literature list at the end of your report that starts on page 39?
MR. COMBS: Object to form.
BY THE WITNESS:
A. I believe I have one or two more articles that I brought with me that I may want to point to today that I've pulled after this list was made.
BY MR. SLATER:
Q. Which articles are those?
A. One specifically is an article on myofascial pain.
Q. Is it listed anywhere in your report or your list of reliance materials?
A. No.
MR. SLATER: Well, I don't have that. So is there any way for that article to be sent to me, Phil?

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MR. COMBS: Yes, we'll figure out some way to send that to you.
MR. SLATER: Okay.
BY MR. SLATER:
Q. What's the other article?
A. That's the only one I specifically have in mind right now.
Q. Who is the author?
A. If you give -- if you want to wait until the break when I un-mike myself, I'll pull it out of my bag.
Q. Sure. We'll just talk about it later.
MR. COMBS: Adam, just bear with me for just one second.
MR. SLATER: I don't want to hold things up. I am not that eager. We can cover it after a break.
MR. COMBS: That's fine. I was just telling Paul to remind me that at the break, we'll get that pdf to you.
MR. SLATER: Thanks.
MR. COMBS: Okay.
MR. SLATER: I'm psyched.
MR. COMBS: Good.
BY MR. SLATER:

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Q. Okay. I am looking still at your reliance list.
After the list of literature there's a list that is a list of what's called "Production Materials," and that list goes I want to say to the end, almost to the end. Let me rephrase it.
In your list of -- your reliance list, after the medical literature list, there is a list of what's called "Production Materials." What is that list?
A. It looks like a list of some memos from Gynecare Ethicon, some publications such as slide decks and monographs and includes anatomy videos.
Q. If we continue through it, it includes Clinical Expert Reports, e-mails, IFUs, TVT documents, TVT-O documents, various patient brochures, various slide decks and videos. Correct?
A. Correct.
Q. Did you read all these documents and watch all these videos?
A. I did not.
Q. Was this a list that was compiled and given to you by counsel?
A. Yes.

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Q. Are you relying specifically on any of these documents for your opinions?
A. I'll be looking to the IFU and the resource monograph as well as --
Q. Anything else?
A. As well as a video on Prolift.
Q. Which video on Prolift?
A. I don't know how to locate it here on this list. It's a 2005 video narrated --
Q. What happens in that video?
A. Pardon?
Q. What happens in that video?
A. It has an animation of pelvic anatomy and then of mesh placement.
Q. And it's an animated video, correct?
A. Correct.
Q. Is that one where the narrator talks about what's happening and you see the mesh arms coming through the exit points and all that sort of thing?
A. Yeah, it's a great description.
Q. Anything else on this list of production materials you're relying on for your opinions?
A. No, those are the ones that come to mind.

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Q. Did you read any depositions of any Ethicon employees?
A. No.
Q. Do you know what standards Ethicon applied in terms of what needed to be included in warnings about the Prolift?
A. No, I don't.
Q. Have you in your career ever been involved in writing or preparing warnings for a medical device?
A. For a company?
Q. Yes.
A. No.
Q. In your practice did you read IFUs for -- rephrase.
In your practice did you read the IFU for each mesh kit before using it?
A. Yes. That was typically my practice.
Q. Did you assume that the IFU was disclosing to you each of the risks and complications the company knew could occur with the kit that you were considering using?
A. No.
MR. COMBS: Object to the form.
BY MR. SLATER:

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Q. What was your answer?
A. No.
Q. Did you assume that when you read an IFU from a company regarding a mesh kit that the company was disclosing to you those complications and risks that could be significant for the patient that were known to the company?
A. No. I always thought of the IFU as helping to delineate steps of the procedure that might be unique to this procedure and to warn of any complications that might not be known to the average surgeon. But it was not something I relied on to know all the complications related to a surgery.
Q. Did you assume that when you read an IFU for a medical device that the company was disclosing any risks and complications that would be inherent to the mesh material so that you would know what those risks were?
A. No. If we were already using the mesh, I would assume I would look to the IFU to tell me what was specific about this delivery system.
Q. Do you know whether or not one of the purposes of the IFU was to disclose each of the risks and complications that can occur with the use

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of that mesh kit in a woman's body?
A. I've never thought an IFU would tell me every risk.
Q. Well, as you sit here now do you have an understanding of any standard whatsoever from any source as to what risks and complications are supposed to be disclosed in an IFU?
A. No.
MR. COMBS: Object to the form.
BY MR. SLATER:
Q. When you're giving your opinions as to whether or not the IFU adequately warns of risks and complications, you're just basing that on your own opinions based on your own experience and what you think is reasonable. Is that fair?
A. That's fair.
Q. You're not relying on any objective standard from any source, correct?
A. Correct.
Q. And you're not corroborating your -- rephrase.
Have you made any effort to corroborate your own opinion as to what needs to be in a warning in an IFU by looking to what Ethicon's professionals believed needed to be in there just

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so you could see whether the standard you were applying was consistent with what someone in the medical device industry would apply? Did you ever do that?
A. No.
MR. COMBS: Object to form.
BY MR. SLATER:
Q. Are you aware of whether there are FDA regulations which provide for what type of information is supposed to be provided in an IFU?
A. No.
Q. Have you looked at any internal documents at all, whether it's an e-mail, whether it's a deposition, anything, from Ethicon or any testimony from anyone in Ethicon, regarding what FDA regulations would require to be disclosed in an IFU?
A. No.
Q. Have you made any effort before today to find out what FDA regulations require a medical device company to disclose in an IFU?
A. No.
Q. Earlier you told me what you expected to see in an IFU. That's -- is it fair to say that's the standard you applied as to what you think needs

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to be disclosed in an IFU?
MR. COMBS: Object to form.
BY THE WITNESS:
A. Yes.
BY MR. SLATER:
Q. In terms of whether or not Ethicon adequately warned, if it turns out that Ethicon had information, which if you applied Ethicon's own warning standards, the standards that their medical people said they were applying and the Regulatory Affairs people said they were applying, and if Ethicon failed to provide that information, would you agree that would be a failure to provide an adequate warning?
MR. COMBS: Object to form.
BY THE WITNESS:
A. No, because I have no idea what their Regulatory Affairs department would think was adequate and whether that was clinically relevant to what I'm doing in surgery.
BY MR. SLATER:
Q. Your background and experience is not necessarily the same as other doctors who use medical devices, correct?
A. Correct.

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Q. And your background and experience is not necessarily the same as that for other physicians who would consider or considered using the Prolift, correct?
A. Correct.
Q. And, in fact, it may be that you might know about a particular potential complication from your experience and another doctor considering using the Prolift might not know about that potential complication, correct?
A. Well, correct, but from my experience and from the literature and attending conferences. So, I'm not relying solely on my experience in my little practice.
Q. Well, this is my question.
MR. SLATER: Well, first of all, move to strike after "correct."
BY MR. SLATER:
Q. Your standard for what needs to be disclosed in the Prolift IFU is not an objective standard where you would say this is the standard across the board that is applied. It's the standard that Dr. Elser has for what needs to be in an IFU. Correct?
MR. COMBS: Object to the form.

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BY THE WITNESS:
A. No, I'd like to think that my standards would be fairly applicable to a pelvic floor reconstructive surgeon.
BY MR. SLATER:
Q. What have you ever done to confirm that your standard for what needs to be in an IFU -- well, rephrase.
Have you ever studied the question of what information needs to be in an IFU? Have you ever engaged in any study of that question?
A. No, I have not.
Q. Have you ever made any effort to confirm that your understanding for what needs to be in an IFU is consistent with what other doctors believe should be in an IFU? Have you ever studied that question?
A. No, I have not.
Q. As you sit here now you don't know whether or not the standard you're applying for what needs to be in an IFU is consistent with what other doctors think. You don't know that because you've never tried to verify that, correct?
MR. COMBS: Object to form.
BY THE WITNESS:

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A. No, but not studying something formally does not mean I haven't discussed IFUs with other similar physicians who have similar practices and take care of patients who need prolapse repairs.
MR. SLATER: Move to strike after the word "no."
BY MR. SLATER:
Q. In doing your work in this case were you curious as to what the Regulatory Affairs department in Ethicon who are the professionals who are required to make sure that an IFU complies with FDA regulations, were you curious what they thought needed to be in an IFU?
MR. COMBS: Object to form.
BY THE WITNESS:
A. No, I was not.
BY MR. SLATER:
Q. You have not reviewed any Ethicon internal documents other than those few that you listed for me, correct?
A. Not that I recall right now related to this case.
Q. Is it fair to say you have no idea what complications and risks were known to Ethicon Medical Affairs and when they were known?

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A. That would be fair.
Q. Would you agree with me that if Ethicon Medical Affairs knew there was a potential risk or complication attributable to the Prolift mesh implant itself which if it occurred could cause severe permanent injury to a woman, that that risk should be disclosed in the IFU? Would you agree with that statement?
MR. COMBS: Object to form.
BY THE WITNESS:
A. No, I don't think it necessarily needs to be in the IFU.
BY MR. SLATER:
Q. Have you ever studied the question of what risks and complications were known to doctors across the country with various backgrounds and levels of experience with regard to the use of the Prolift? Did you ever study that question?
A. No.
Q. And you don't know the answer to that question, correct?
A. Correct.
Q. One of the references in your article is the Blandon article from some doctors at the Mayo Clinic, correct?

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A. Correct.
Q. Would you agree that the scope of complications and the consequences of those complications which the doctors talk about as life-altering and other very severe language, those profiles apply to the Prolift, meaning some women suffer complications that severe from that device?
A. I don't recall that language from the article specifically. So, I would like to look at the article before answering you.
Q. Do you recall that in the Blandon article they talk about complications including complex mesh erosions, pain syndromes, dyspareunia, the need for multiple surgical interventions to treat complications, life-changing symptoms, complex mesh erosions at multiple sites, most patients with erosions require surgery, multiple attempts to excise mesh may be required, life-changing complications, incapacitating pelvic pain, dyspareunia and large-scale erosions that are exceedingly complex and not easily resolved, do you recall language to that effect in that article?
MR. COMBS: Object to form.
BY THE WITNESS:
A. I don't know what you're reading from.

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So, I would like to have the article in front of me before I can answer you.
BY MR. SLATER:
Q. Let me ask you this question. Do you agree with me that one of the risks with the Prolift is complex mesh erosions?
A. Can you define "complex mesh erosion"?
Q. Have you never heard that term used before?
A. It's -- it's not a standard term. So, I don't know what you mean by that.
Q. Are you not familiar with seeing the term "complex mesh erosions" in the medical literature?
A. It's -- again, it's not a standard form, so everyone may have a different definition of that. How are you using it?
MR. SLATER: Move to strike.
BY MR. SLATER:
Q. My question is this: Do you not recall seeing the term "complex mesh erosions" in the medical literature?
A. I may have. But in my practice I don't describe things that way so I don't know what you mean by it.

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Q. I'll define a complex mesh erosion as one that is complex to treat. Do you agree that that is a risk with the Prolift?
MR. COMBS: Object to form.
BY THE WITNESS:
A. Okay. We would have to debate what "complex to treat" means, but any mesh can be complex to treat as can pain after native tissue repair.
MR. SLATER: Move to strike.
BY MR. SLATER:
Q. Doctor, I didn't ask you about native tissue repair. So I would appreciate if you wouldn't talk about it when I don't ask about it because it's not helpful for us finishing on time, please.
Do you agree with me that if I define "complex mesh erosion" as one that is complex to treat, meaning it's not a routine, easy procedure, do you agree that is one of the risks with the Prolift?
MR. COMBS: Object to form.
BY THE WITNESS:
A. Yes, I agree that pelvic mesh can be complex to treat.

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BY MR. SLATER:
Q. Do you agree that one of the risks with the Prolift is that the Prolift can lead to a chronic pain syndrome?
A. Yes.
Q. Do you agree that one of the risks with the Prolift is that the Prolift can cause dyspareunia?
A. Yes. Again, not specific to Prolift, but any mesh and any vaginal surgery, although you don't want me to mention any vaginal surgery.
MR. SLATER: Move to strike after the word "yes."
BY MR. SLATER:
Q. Do you agree with the Prolift that one of the risks is the need for multiple surgical interventions to treat the complications?
A. Yes.
Q. Do you agree that one of the risks with the Prolift is that the woman can sustain life-changing symptoms?
A. Yes.
Q. Do you agree that with the Prolift one of the risks is complex mesh erosions at multiple sites?

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MR. COMBS: Object to form.
BY THE WITNESS:
A. Yes, there can be erosion at more than one site after mesh is placed.
BY MR. SLATER:
Q. Would you agree with the Prolift that the literature shows that most patients with erosions require surgery?
A. In that article.
Q. Would you agree that with the Prolift most women who have erosions, the majority end up needing surgery?
A. No.
MR. COMBS: Object to form.
BY MR. SLATER:
Q. You said no?
A. I said no. That was the experience of these patients in this Mayo Clinic experience, but that is not reflected in the other literature or necessarily in clinical experience.
Q. With the Prolift would you agree that multiple attempts to excise mesh may be required, that's one of the risks?
A. Yes.
Q. Would you agree that one of the risks

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with the Prolift is life-changing complications?
A. I think you already asked about life-changing changes, right? Is this a different question?
Q. It is. I asked you about life-changing symptoms before. Now I'm asking you a new question.
My question is this: Do you agree with the Prolift one of the risks is life-changing complications?
A. Okay. I'm having trouble understanding how that's a different question.
Q. Do you agree that life-changing complications is one of the risks with the Prolift? Do you agree to that statement?
A. Yes.
Q. Do you agree that one of the risks with the Prolift is incapacitating pelvic pain?
A. Yes, patients can have severe pain after pelvic mesh is placed and after pelvic surgery.
MR. SLATER: Move to strike after the word "yes."
BY MR. SLATER:
Q. Do you agree that one of the risks with the Prolift is large-scale erosions that are

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exceedingly complex and not easy to resolve?
MR. COMBS: Object to form.
BY THE WITNESS:
A. By "large-scale" do you mean a large area in one patient or a large scale meaning lots of people in the population?
BY MR. SLATER:
Q. Large area in the patient.
A. Mesh can have a large area of erosion.
Q. The list of complications and risks I just asked you about, do you know whether Ethicon knew about those risks on the day the Prolift first went to the market?
A. I don't know.
Q. If Ethicon knew about that scope of risks that I just went through with you on the day the Prolift went to the market, do you agree those risks should have been disclosed in the IFU?
MR. COMBS: Object to form.
BY THE WITNESS:
A. No. The pelvic surgeons were already familiar with placing vaginal mesh.
BY MR. SLATER:
Q. When the Prolift came out on the market, surgeons were not experienced on any long-term

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basis with the use of mesh kits like the Prolift with that much mesh going into those parts of the body, this was something new at that point, correct?
A. The obturator-based placement with the mesh arms was new. It doesn't mean that large pieces of mesh were not used for prolapse repair before this.
MR. SLATER: Move to strike after the word "it."
BY MR. SLATER:
Q. Do you know the area of mesh used in the Prolift, in any of the Prolift kits?
A. Not offhand.
Q. Would you agree with me that as compared to the way that mesh was used before the Prolift came along that the Prolift provided for more mesh to be put in a woman's pelvis than what had been previously used?
A. Yes, for the most part.
Q. Do you have any information as to whether the amount of mesh with the Prolift increases the risk of harm to the woman?
A. No.
Q. Do you have an opinion one way or the

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other or no opinion on that question?
A. No opinion.
Q. Do you know whether or not the amount of mesh placed in the woman's pelvis for treatment of prolapse has an impact on the intensity and duration of the foreign body reaction and inflammatory response?
A. No.
Q. Do you have any opinion on that question?
A. No, I don't.
Q. Am I accurate you do not hold yourself out as an expert with regard to the design of medical device kits for the treatment of prolapse?
A. That would be correct.
Q. And am I correct that I would not expect you to offer opinions as to the design of the Prolift?
MR. COMBS: Object to form.
BY THE WITNESS:
A. I may offer opinions.
BY MR. SLATER:
Q. Am I correct that you do not hold yourself out as having expertise or specialized knowledge regarding the type of mesh used in the

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Prolift?
A. Outside of the Amid classifications, no.
Q. Do you have any expertise or specialized knowledge regarding whether or not a 1 millimeter pore size when the mesh is in use in the body has any advantages or disadvantages for the patient?
MR. COMBS: Object to form.
BY THE WITNESS:
A. As opposed to other sizes in general or bigger or smaller? Do you want to be more specific?
BY MR. SLATER:
Q. Do you have any -- any specialized knowledge or expertise regarding whether or not a 1 millimeter pore size for the Prolift in actual use has any significance for safety for the woman?
A. Well, in general we want pore size of the type 1, which is greater than 75 microns, to allow for adequate tissue ingrowth and allowing white blood cells in the area.
MR. SLATER: Move to strike.
BY MR. SLATER:
Q. Here's my question. Are any -- do you have any opinion -- I'm sorry. Don't -- let's not do that.

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MR. COMBS: And what's your reference? Let's not do what? What are you talking about?
MR. SLATER: You know, I'm not going to say anything for the record. Let's just be careful how we proceed.
MR. COMBS: I have no idea what you're talking about. If there is something you want to raise, feel free to raise it. If not, let's just move forward.
MR. SLATER: All right. Well, if you're going to challenge me, Dr. Elser is continually looking at you.
MR. COMBS: Looking at me?
MR. SLATER: I think so.
MR. COMBS: Okay. Well, I wasn't aware of that.
THE WITNESS: I'm trying to look at --
MR. SLATER: You are wasting time with the questioning. I wasn't looking to get into it.
MR. COMBS: Let's just move on.
MR. SLATER: Don't laugh. I'm sorry if I am amusing you.
MR. COMBS: Who are you talking to?
MR. SLATER: You.
MR. COMBS: What --

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BY MR. SLATER:
Q. Dr. Elser. My next question is this: Am I correct that you do not hold yourself out as an expert with regard to whether or not a 1 millimeter pore size in the Prolift when the mesh is actually in use is significant in terms of safety or effectiveness?
MR. COMBS: Object to the form, asked and answered.
BY THE WITNESS:
A. In my reading of literature, the type 1 greater than 75 micron diameter pore size is right now the optimal mesh to use in a patient. Outside of that, I don't know what you're asking.
MR. SLATER: Move to strike.
BY MR. SLATER:
Q. I didn't ask any questions about Amid type 1. I will, I promise, in a couple minutes. But I didn't ask about that. I will try my question again.
Am I correct that you do not hold yourself out as an expert with regard to any implications -- rephrase.
Am I correct that you do not hold yourself out as an expert with regard to whether a

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mesh pore size in a Prolift of either greater or less than 1 millimeter when the mesh is under strain in use has any significance with regard to safety or effectiveness? Am I accurate, you do not hold yourself out as having any expertise with regard to that question?
MR. COMBS: Object to the form, asked and answered.
BY THE WITNESS:
A. Well, I think your word "any" is a little troublesome for me there. So...
BY MR. SLATER:
Q. Let me ask you the question this way. What, if any, significance is there to whether or not the pore size of the Prolift is 1 millimeter when the mesh is actually in use in the body? Do you have any knowledge of that?
MR. COMBS: Object to the form, asked and answered.
MR. SLATER: It has not been asked and answered. That's not fair.
BY MR. SLATER:
Q. Please answer the question.
A. I may have opinion on that.
Q. What is it?

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A. Well, I -- we want to place the 75 micron pore size --
Q. I didn't ask you about 75.
A. -- without undue tension.
MR. COMBS: Right now we are not going to do this. Dr. Elser is --
MR. SLATER: -- your expert continually obstruct this deposition by not answering a simple answer. All she wants to talk about is Amid type 1 and I haven't asked any questions about it.
MR. COMBS: We are going to start with a basic rule of civility that you're going to let me --
MR. SLATER: I don't want to be lectured.
MR. COMBS: I'm just telling you right now we'll just take a break. If you're not going to allow me to finish my statement or the witness to finish her statement, we're just going to quit.
Now, you need to let the witness finish her answer. You can move to strike it if you don't like it. But don't interrupt her and don't interrupt me. I'm not interrupting you.
MR. SLATER: Well, you are right now. You are interrupting the whole flow and killing time. You need to instruct your witness with all due respect -- it's my understanding Judge Eifert

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expects it -- that she needs to answer my questions and not go off on talking points.
MR. COMBS: She has answered your question multiple times.
MR. SLATER: She has not. It's very frustrating because it's not being answered. I haven't gotten one answer about 1 millimeter pore size yet.
BY MR. SLATER:
Q. I'll do this. I'm going to do something for you, Dr. Elser. Let me ask you this.
Do you think and are you forming opinions based on the assumption that the only standard for pore size that matters is whether or not the pore size is Amid type 1, which is 75 microns? Is that true?
A. That is what's in the urogyne literature and you asked about what pore size under tension, which is different. So, I may have opinions on that. But I -- I'd like you to be more specific in your questioning about that. I imagine you're going to ask me something else.
MR. SLATER: Move to strike.
BY MR. SLATER:
Q. Doctor, are you aware that Amid doesn't

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think that his standard applies to the type of mesh used in the Prolift?
A. No.
Q. If that's the truth, that would undercut a portion of the basis for your opinions, wouldn't it?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. No, because other literature uses Amid's classification in talking about mesh in the urogyne and urology literature, not Dr. Amid himself.
BY MR. SLATER:
Q. Are you aware that they're using the term wrong, in the wrong context because they don't understand it?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. No, I don't know what you mean by that.
BY MR. SLATER:
Q. Have you ever studied specifically the question of whether or not a 1 millimeter pore size under strain is of any significance with the Prolift?
A. No.
Q. Am I accurate you have no opinions on

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that specific question?
MR. COMBS: Object to the form, asked and answered.
BY THE WITNESS:
A. No, I may have opinions if you ask me a question in a different way later. But right now, no.
BY MR. SLATER:
Q. On the question I just asked you I'm correct, you have no opinion on that question, right?
MR. COMBS: Object to the form, asked and answered.
BY THE WITNESS:
A. Same answer.
BY MR. SLATER:
Q. The answer is you have no opinions on that specific question, correct?
A. At this time.
Q. Do you know what Ethicon internally thought about the significance of whether or not the pores in the Prolift would be greater than 1 millimeter when the mesh would be under tension in actual use?
A. No.

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MR. COMBS: Object to the form.
BY MR. SLATER:
Q. You have no knowledge on that, right?
A. Correct.
Q. Would you defer to the scientists at Ethicon with regard to that question?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. Would I defer to them for its clinical meaning?
BY MR. SLATER:
Q. Sure. Yes.
A. That -- I would consider that as part of the information we would take into consideration.
Q. Have you read any articles that you could point to as you sit here now that discuss the significance of a 1 millimeter pore size in a mesh for use in treating a prolapse?
A. Not that I can point to right now.
Q. If Ethicon internally thought that caution should be used by a doctor in deciding whether or not to use a Prolift with a patient, should that information have been in the IFU?
MR. COMBS: Object to the form.
BY THE WITNESS:

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A. I'm sorry. Can you word it again.
BY MR. SLATER:
Q. If Ethicon Medical Affairs, if any -- rephrase.
If someone in Ethicon Medical Affairs believed that caution needed to be taken by a doctor before using a Prolift in particular women, should that information have been put in the IFU?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. That seems very vague. So I'll say no.
BY MR. SLATER:
Q. If -- if Ethicon Medical Affairs believed that caution should be used before putting a Prolift into a woman based on some fact about her background or her demographics or her age or her level of prolapse or something about her co-morbidities, anything like that that was specific that could be related to specific patients, should that information have been in the IFU so doctors would have that information in deciding what to offer their patients?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. No. And, again, I look to the IFU for

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some specific product-related procedural steps and some information on product but not for all of the precautions. I look to the literature and experience and attending conferences for the full picture.
BY MR. SLATER:
Q. Well, you realize there is doctors who were using the Prolift who had not attended conferences where they were lectured about who the Prolift should be used for, right?
A. Yes.
Q. So, they couldn't be expected to have that information, right?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. The information is in the literature because material at conferences is published. There is access.
BY MR. SLATER:
Q. There are some physicians who don't read very much medical literature because they are busy clinical practitioners and don't read very much literature. That's a known fact, correct?
A. That's a known fact. Now, whether -- I mean, as an implanter of a permanent mesh in a

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patient, I want to be aware of at least some literature knowing what to expect before I would implant it in a patient.
MR. SLATER: Move to strike after the word "fact."
BY MR. SLATER:
Q. Are you aware one way or the other of whether doctors relied on the IFU to tell them each of the significant risks and complications known to Ethicon?
A. No. And I've never met a doctor who I've discussed IFUs with that ever said they used an IFU as their sole source of information.
MR. SLATER: Move to strike after the word "no."
MR. COMBS: Adam, we have been going now for over an hour. Let's -- let's wrap up sometime in the next five minutes and take a break.
MR. SLATER: You need a break?
MR. COMBS: Well, sometime in the next five minutes.
MR. SLATER: Okay.
BY MR. SLATER:
Q. Doctor, do you have any information as to what level or grade of prolapse Ethicon

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internally believed the Prolift should be limited to the use of?
A. No.
Q. If Ethicon internally believed the Prolift should be limited to stage 3 and stage 4 prolapse, you don't know about that, right?
A. No, I think that's our call as surgeons to know what stage prolapse deserves or is a candidate for a mesh augmentation.
MR. SLATER: Move to strike after the word "no."
BY MR. SLATER:
Q. Do you know what level of prolapse the inventors of the prolapse thought the Prolift should be used with?
A. No.
Q. Do you know whether the inventors of the Prolift ever indicated in anything they published whether or not they thought the Prolift was an appropriate treatment as a primary treatment for a sexually active woman?
A. No.
Q. Do you know whether Ethicon Medical Affairs thought that caution should be shown before the Prolift would be used in a sexually active

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woman?
A. No.
Q. If Ethicon Medical Affairs thought that caution should be used before the Prolift should be used in a sexually active woman and that was thought even before the Prolift first went on the market in March of 2005, you would agree that information should have been in the IFU, right?
A. No.
MR. COMBS: Object to the form.
BY MR. SLATER:
Q. And in March of 2005, doctors didn't have extensive experience with the use of the Prolift or kits. This was very new. So, at that point if Ethicon knew about risks or complications or relative contraindications or that caution should be used or anything like that, at that time point it would have been important to put that information in the IFU because this was the early days of the use of the Prolift, correct?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. No, this is not -- there was caution that there should be surgeons familiar with pelvic reconstructive surgery and the use of permanent

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implants in the pelvis. That warning was in there.
So, physicians familiar with pelvic reconstruction and the use of permanent implants should have -- would have the clinical knowledge of being wary of using this product in sexually active women if they felt that was a population that might or might not be used in.
MR. SLATER: Move to strike after the word "no."
We can take a break.
MR. COMBS: Okay.
THE VIDEOGRAPHER: Okay. The time is 11:50 a.m., and we are going off the video record.
MR. SLATER: Ten minutes.
MR. COMBS: Yeah. Let's talk briefly about lunch.
(WHEREUPON, a recess was had from 11:50 a.m. to 12:02 p.m.)
THE VIDEOGRAPHER: The time is 12:02 p.m. and we are back on the video record.
BY MR. SLATER:
Q. Doctor, in your report, there's the list of medical literature Ethicon provided you the list of. You didn't read all those articles and references, did you?

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A. No.
Q. Did you assume that Ethicon is familiar with clinical data, whether published or unpublished, that could be significant to assessing the safety and effectiveness of the Prolift that they would have provided that to you so you could consider it?
A. That's such a broad question.
Q. What's broad about it?
A. That they would give me a list that has comprehensive every single thing that they know might have happened to the Prolift?
Q. It's not what I asked. So I will try it again.
A. Okay. Let me try and listen better, then.
Q. If Ethicon knew of a particular clinical study for which data was presented at an important medical meeting with regard to safety or efficacy of the Prolift, would you have liked to have seen that?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. Yes, I would like to have seen it. I don't know that I would rely on everything that's

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been presented at any meeting related to Prolift.
MR. SLATER: Move to strike from "I don't know" going forward.
BY MR. SLATER:
Q. Unless you would see such data, you couldn't assess whether or not it was significant to you in forming your opinions, correct?
A. No, but it would be one piece to add to all of the knowledge and literature that we have in the -- I have considered.
MR. SLATER: Move to strike after the word "no."
BY MR. SLATER:
Q. It's possible that there is clinical data you didn't see which if you saw it could change your opinions in this case. That's possible, right?
A. Yes. It's possible, but I'm relying on lots of literature and clinical experience to form my opinions and I don't think --
Q. Move to strike.
A. -- there is any one article that is going to change my mind.
MR. SLATER: Move to strike from "but" forward.

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BY MR. SLATER:
Q. Did you deliberately not cite to articles that were unfavorable to the Prolift?
A. Did I deliberately. I don't think I deliberately chose not to cite -- I didn't look at an article and say I don't want to cite this one. I looked for articles I knew of that had facts I wanted in my report.
Q. Are you familiar with the article published in the American Journal of Obstetrics and Gynecology in February of 2014 where the first named author is Sara Abbott?
A. Sara Abbott. I have heard of it, but I would need to look at it to answer any questions on it right now.
Q. Have you read that article?
A. I need to look at it to answer that question.
Q. I don't see it listed anywhere in your report, so you have it there but you didn't list it?
A. I don't have it here. I said I would need to look at it to answer it.
Q. This is my question since I only get to depose you once for this case.

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As you sit here now did you read that article?
A. My answer is I may have read it. I don't recall right now.
Q. Do you recall as you sit here right now whether there was anything of significance in that article that could be significant to the opinions you've reached in this case?
A. I don't recall. If you want us to pull it at the break, I will be happy to answer questions about it.
Q. I don't want to pull it at the break because you didn't include it anywhere -- rephrase.
You did not reference the Abbott article anywhere, correct?
A. In this report, no.
Q. If Ethicon said something in the IFU which Ethicon knew not to be true, would you agree that that would be wrongful?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. Yes, I think that would be strange.
BY MR. SLATER:
Q. Well, would it be wrongful?
MR. COMBS: Object to the form.

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BY THE WITNESS:
A. On the surface, yes.
BY MR. SLATER:
Q. If Ethicon made claims about the mesh in the Prolift that Ethicon had no data to support, would that be wrongful?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. I'm having trouble answering this because I'm trying to imagine reading an IFU and knowing what was said about the mesh that didn't have claims to support it.
Descriptions of procedures are -- in an IFU doesn't necessarily have data behind it necessarily. I don't know. I don't know what you're trying to ask really.
Q. Are you aware of anything in the Prolift IFU as to which anyone in Ethicon had admitted there was not data to support the claim about the mesh? Are you aware of that occurring?
A. No.
Q. Are you aware of Ethicon in deposition testimony admitting anything about the mesh which is contrary to what was represented in the IFU?
A. No.

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Q. If either of those things occurred, would you agree that would be a failure to provide adequate and appropriate warning to doctors about the Prolift?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. No.
BY MR. SLATER:
Q. So, it's okay for Ethicon -- rephrase.
So, it's not a failure to warn even if Ethicon provided information about the mesh it knew to be unsupported or it made an affirmative representation about the mesh that it knew not to be true, that's okay with you?
A. My answer is yes because I -- I'm imagining circumstances where one person -- such a big company, one person in the company said one thing that may not be clinically applicable to what pelvic reconstructive surgeons are using the mesh for.
Q. You have absolutely no idea how Ethicon creates the IFU or how the information is put into the IFU, you have no idea, right?
A. No, I don't.
Q. You have no idea about who has to

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confirm the accuracy and the truthfulness of the information in the IFU before it's actually printed and put into the box. You have no idea on that, right?
A. That's correct.
Q. And just to be clear, it's acceptable to you if Ethicon -- rephrase. Withdrawn.
I want to just go back to your report for a couple minutes. The last few pages of Attachment B. The third-to-last page, it says "Publicly Available." There are publicly available documents. Do you see that?
A. Yes.
Q. Did you compile that list or was that compiled for you by counsel?
A. I don't remember because I pulled most of these things and I don't recall if this was provided for me.
Q. Are you relying on any of the materials on the "Publicly Available" list to form your opinions?
A. They add to my opinions, yes.
Q. Sorry. Say that again.
A. Yes, I've read most of these and they would help form my opinion, yes.

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Q. You're familiar with Committee Opinion 513, the joint opinion of ACOG and AUGS, correct?
A. Yes.
Q. Was that of significance to you in forming your opinions in this case?
A. It was part of what I used to form my opinions, yes.
Q. And you feel that the conclusions found in that committee opinion are applicable to the Prolift, correct?
A. For the most part.
Q. What do you do, do you pick the ones that -- well, rephrase.
When you say "for the most part," which ones aren't applicable to the Prolift? Which conclusions in 513 are not applicable?
A. Okay. I need to open it in front of me to answer specifically, but my biggest -- the fact that AUGS and ACOG put it out doesn't mean I agree with everything that they said.
So, my biggest complaint out of that document was the need to have a randomized controlled trial of a vaginal mesh kit to a native tissue repair because to me I'm not necessarily going to use those two approaches on the same

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patient population. So, it didn't make sense to me how a large-scale RCT was going to solve this question for me or for my patients.
Q. Actually in your report you cited to the portion of the Committee Opinion 513 that said that the mesh kit should be used only in high-risk individuals for which other options are not available or appropriate. You agree with that conclusion?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. They should be -- they are -- that's one of the considerations taking in. I don't -- I object to "should be used." I don't know that I would agree with that.
BY MR. SLATER:
Q. Well, you agree that the Prolift should only be used in women for whom other approaches and other alternative treatments are not reasonable options. Do you agree with that?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. No, because they may be reasonable options and a patient has a choice, has some input into what she chooses, one or the other, after

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being counseled.
BY MR. SLATER:
Q. If one were to apply the Committee Opinion 513 patient selection criteria, Ms. Bellew would not meet that criteria and would be excluded, correct?
A. No.
Q. I'm not correct?
A. Correct. Right. My -- she did not meet the criteria to have vaginal mesh placed?
Q. That's not my question. Let me ask this: Dianne Bellew was an acceptable candidate to have nothing done. That was one of her options, right?
A. Right.
Q. Dianne Bellew was an acceptable candidate for an anterior colporrhaphy simply with native tissue and suture, correct?
A. Correct.
Q. Dianne Bellew was not a high-risk individual for whom treatments other than the Prolift were not available or indicated, correct?
A. No. She has emphysema.
Q. She what?
A. She has emphysema and she's a smoker.

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MR. SLATER: Move to strike.
BY MR. SLATER:
Q. Ms. Bellew, if you apply -- rephrase.
If you applied Committee Opinion 513 to Ms. Bellew as she first went to Dr. DeHasse, she's not one of those high-risk individuals for whom procedures other than the Prolift would not have been available options, correct?
A. No, not necessarily. She has -- she's a smoker with emphysema.
Q. And which procedure -- well, rephrase that.
The fact that Ms. Bellew was a smoker would not exclude her from being a candidate for anterior colporrhaphy with sutures, correct?
A. Well, it's certainly someone I would counsel. She's at higher risk than a non-smoker without emphysema for recurrence, an early recurrence after a native tissue repair.
Q. Ms. Bellew never had a recurrence, did she?
A. No.
Q. The only time that sutures had to be placed was after Dr. DeHasse realized after she removed a significant amount of mesh from the left

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arm that there was now a defect that needed to be shored up so that what was now a stage 1 prolapse wouldn't become worse, that's the only time sutures needed to be used, correct?
A. In order to fix a prolapse repair you're saying?
Q. Yes.
A. Yes. And it would be really great if we could look at every patient and say you are going to recur if I use native tissue or you are not. We can only look at risk factors and tissue quality.
MR. SLATER: Move to strike from "and" forward.
BY MR. SLATER:
Q. Let me ask you this about smoking. Do you know that Ethicon was advertising and marketing the Prolift to smokers?
A. No.
Q. Do you know that at the time Ms. Bellew was consented for the procedure there was no warning in the IFU as to smoking creating any increased risk for her?
A. I would have to look at that particular IFU. But I would like to make a distinction between smoking as a risk factor for recurrence and

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smoking as a risk factor for erosion exposure.
MR. SLATER: Move to strike.
BY MR. SLATER:
Q. The IFU that was in effect when Ms. Bellew had her surgery did not mention smoking as a risk for anything, correct?
A. I would have to look at it to say which IFU contained that.
Q. You don't know as you sit here now, do you?
A. Right, I don't recall that one.
Q. Ms. Bellew had granulation tissue about a month or so after the surgery and that was treated by Dr. DeHasse, correct?
A. Yes.
Q. The mesh was likely a contributing factor to the development of that granulation tissue, correct?
A. I don't know.
Q. You don't have an opinion one way or the other on that?
A. No, could happen at the site of the suture. It happens more often in smokers. So, we don't know if the mesh contributed.
Q. I just want to know you're not forming

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an opinion on that, correct?
MR. COMBS: Object.
BY THE WITNESS:
A. A suture or mesh is a risk factor for granulation tissue.
BY MR. SLATER:
Q. So, it's possible that the mesh contributed to the granulation tissue, correct?
A. It's possible.
Q. Beyond that, you're not forming an opinion with regard to the cause of the granulation tissue, correct?
A. Right. We don't know what caused it.
Q. In 2011 and 2012 Dr. DeHasse operated three times on Ms. Bellew, correct?
A. Say the dates again.
Q. In 2011 and 2012 Dr. DeHasse operated three times on Ms. Bellew, correct?
A. Yeah.
Q. Each time Dr. DeHasse found what she described as sclerosed, hardened mesh, correct?
A. Yes.
Q. You would agree that is mesh that had scar plates across it that was creating contraction and hardening of the mesh, correct?

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MR. COMBS: Object to form.
BY THE WITNESS:
A. I'm not sure what you mean by scar plates, but there certainly was scarring and fibrosis in the area of the mesh.
BY MR. SLATER:
Q. Do you know what the term "scar plate" means?
A. No.
Q. You've never seen that term?
A. I've seen it, but I don't know the definition.
Q. Do you know whether the term "scar plate" had any significance for Ethicon internally among its doctors and scientists?
A. No.
Q. The hardening and the formation of the scar tissue -- well, rephrase.
You would agree that the mesh through that process of the scar tissue and fibrosis forming on the mesh would have also been accompanied by contraction of the mesh, correct?
A. It can be, yeah.
Q. I'm sorry?
A. Yes, it can be.

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Q. In this case it's more likely than not that Ms. Bellew's Prolift mesh was contracted, correct?
A. At that site where it was felt to be sclerosed, yes.
Q. The contraction and the sclerosis and the hardening of the mesh that was removed from Dr. DeHasse, that occurred due to the fact that the mesh was in Ms. Bellew's body and this occurred due to the Prolift mesh, correct?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. I just want to make one little correction because I don't know how picky you are, but you said "removed from Dr. DeHasse" and I'm going to assume you mean "by Dr. DeHasse."
Q. Yes.
A. Okay, thanks, because I don't know anything about Dr. DeHasse having surgery.
Can you ask me again.
Q. Sure. The contraction and the fibrosis and the hardened scar tissue forming across the mesh, that occurred and was caused by the Prolift being in Ms. Bellew's body, correct?
MR. COMBS: Object to the form.

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BY THE WITNESS:
A. Yes, most likely because it was found in the area of the mesh arm, but we can see --
BY MR. SLATER:
Q. Dr. DeHasse confirmed clinically Ms. Bellew was feeling pain and tenderness in the area where the mesh was contracted and sclerosed, correct?
A. Yes, she felt on exam that the area of sclerosis reproduced pain.
Q. And you in your opinion would agree that it's more likely than not the contracted sclerosed mesh was causing pain and tenderness for Ms. Bellew, correct?
A. Yes.
Q. And you would agree with me that each of the surgeries that were performed by Dr. DeHasse in 2011 and 2012, the three mesh excision surgeries, occurred and were caused by the fact that the Prolift was in Ms. Bellew's body, had developed the contraction and the sclerosis, was causing her pain and needed to have the mesh removed, correct?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. Yes. It was most likely that she was --

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had pain at the area of the mesh arm where there was some fibrosis and scarring and the treatment -- part of the treatment was removal of that arm of the mesh.
BY MR. SLATER:
Q. Dr. DeHasse testified that she believes that this is a progressive situation where the fibrosis and the contraction continues to occur with the Prolift mesh. You would agree with that, correct?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. No, I would not.
BY MR. SLATER:
Q. You're saying it's possible it is, it's possible it's not. You don't know at this point, correct?
MR. COMBS: Objection to form.
BY THE WITNESS:
A. I would say that no, it is likely not.
BY MR. SLATER:
Q. Well, there is a possibility that there is going to be further contraction and hardening and sclerosis of the mesh that could cause more pain and need -- and cause more surgery in the

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future. That's possible, right?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. It's possible but unlikely.
MR. SLATER: Move to strike from "but" forward.
Just checking my notes to try to move through this a little quicker.
BY MR. SLATER:
Q. You would agree with me that the complications that were treated by Dr. DeHasse on July 27, 2011, on October 6, 2011 and July 12, 2012, the three excision surgeries, that those complications were due to the Prolift, correct?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. As it pertains to excising the fibrosed area of the mesh, because she also had abdominal surgery on the 12th, in July of '12.
BY MR. SLATER:
Q. I'm talking about with regard to the mesh.
A. Yes, she had some -- she had fibrosis around the site of the left mesh arm that was excised.

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Q. And you'd agree those surgeries were indicated and appropriate, correct?
A. Yes.
Q. And you'd agree that the indication for the surgery, at least in part, was that this hardened, sclerosed mesh was causing pain for Ms. Bellew and that was a part of the appropriate indication for those three surgeries, correct?
A. Yes. That's part of the treatment for that problem.
Q. You would agree with me that there was a chronic foreign body reaction to the Prolift mesh in Ms. Bellew's body, correct?
A. I don't comment on that because I did not read the pathology report.
Q. So, you have no opinion one way or the other on that question?
A. That's correct.
Q. Are you aware of whether or not the Prolift causes a chronic foreign body reaction in a woman's body?
A. Yes, as far as I know, foreign bodies cause foreign body reaction for the most part.
Q. If I read your report correctly, it's my understanding that you believe that Ms. Bellew may

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have two issues vaginally at this point, some scarring in her vagina from the surgeries and myofascial pain in her pelvic floor. Do I understand that correctly?
A. Yes.
Q. And am I correct that those would both be causally related to the Prolift being in her body and the multiple surgeries to remove portions of the mesh?
A. No.
Q. Well, certainly those surgeries and the presence of the Prolift would contribute to the scarring in the vagina that causes discomfort and pain to Ms. Bellew, correct?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. No. My opinion is that the myofascial disorder is most likely causing her pain at this point and that's -- until that's treated we can't comment on how much the scar is contributing.
BY MR. SLATER:
Q. So, with regard to the scarring in Ms. Bellew's vagina, you're not forming an opinion one way or the other as to whether or not that's causing her pain currently?

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A. I will say that, yes, it was an area around the left sulcus as described by Dr. Elliott as being tender on exam but he doesn't describe a scar there.
And even if there is a scar there, if there's hypertonic muscles in that area pulling on the scar, the scar might be tender, but not the primary source of pain, because until you address that muscle tone we can't tell if the scar is going to be a problem or not.
Q. So, with regard to the scarring in the vagina, you're not giving an opinion at this point as to whether or not that's contributing to Ms. Bellew's complaints of pain in her vaginal area, correct?
A. No, at this point I think her myofascial problem is her primary problem and she -- of course she has a scar in her vagina. She's had surgery. I believe it's less likely --
Q. With regard to the myofascial pain, that is causally related to the fact that the Prolift was in Ms. Bellew's body, it had to be removed with three operations, correct?
A. I don't -- no, I don't agree with that.
Q. Certainly the fact that the Prolift was

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in Ms. Bellew's body, the fact that it had this inflammatory reaction, it was hardened, contracted and then three operations were performed through the vagina to remove mesh, that would be a contributing factor contributing to the myofascial pain, correct?

MR. COMBS: Object to the form.

BY THE WITNESS:

A. Correct, in that it may contribute to the pain but she had sclerosing and fibrosis of one particular area of the mesh. A very limited surgery was performed to remove that area. That area no longer has any sclerosing or mesh palpable. And she had preexisting dyspareunia before the surgery and she has chronic myofascial pain in many other parts of her body.

So, I don't know what was preexisting, what was caused by having a hysterectomy or what to what degree having had a prolapse surgery or mesh placed contributed to her myofascial pain that she experiences now.

Q. If I understand your answer, the Prolift being in Ms. Bellew's body and the three operations to remove it could be a contributing factor, one contributing factor to the development of the

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myofascial pain in her pelvic floor. Fair statement?

MR. COMBS: Object to form.

BY THE WITNESS:

A. Yes.

BY MR. SLATER:

Q. It's certainly likely that it's contributing to some effect, some extent, correct?

A. At this point I don't know because she had the offending area removed.

Q. Well, it's certainly likely that the Prolift being in her body and the three operations to excise the contracted mesh contributed to the development of the myofascial pain condition, correct?

A. No, except any pelvic surgery can cause a flare of myofascial pain and I can't say that the fact that she has Prolift there now with the sclerosed area removed is a contributing factor at this point.

MR. SLATER: Move to strike.

That's not my question. Let me just try to ask it better.

BY MR. SLATER:

Q. Would you agree with me that the course

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Ms. Bellew went through of three operations to remove portions of the mesh going through those three operations contributed to the development of the myofascial pain syndrome?

A. No.

Q. You're saying it's possible that it contributed but you can't say more than that?

A. Correct.

Q. Ms. Bellew had no findings of myofascial pain before the Prolift surgery, correct?

A. No.

Q. I'm correct, right?

A. No, you're not correct.

Q. Ms. Bellew -- new question.

Ms. Bellew had no symptoms, complaints or findings of myofascial pain or spasm in her pelvic floor before the surgery, correct? I'm only talking about the pelvic floor now before the Prolift.

A. No, the answer is we don't know. She had complaints of pelvic pain, abdominal pain; and I don't see an assessment of the pelvic muscle tone on the initial evaluation so I don't know what she had.

Q. The only indication of any pelvic or

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vaginal pain or discomfort before the Prolift surgery was -- you referred to it in Dr. Leano's record, that when she went to the emergency room last week, and this is May 20, 2009, when she went to the emergency room last week with complaints about abdominal and vaginal pain she was told her bladder had fallen. That's the one note, correct?

MR. COMBS: Object to form.

BY THE WITNESS:

A. That's the one note in the medical records, correct.

BY MR. SLATER:

Q. And what that's referring to is when the cystocele formed and the -- and Ms. Bellew first became aware of it, she complained of this causing her pain and discomfort and this abnormal sensation where it said it felt like she had a tampon dropping into her vagina, correct?

A. Yes, but I -- it's very unlikely that a second degree cystocele causes pain that would take someone to the emergency room. So it's very possible that she had myofascial pain that was not assessed. That's not something that typically an ER doctor would ever address on pelvic exam.

So, they saw a cystocele and told her

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that was her finding because that would be the level of evaluation expected from an emergency room physician.

So, I still don't have anyone that's told us what is the state of her pelvic muscles prior to that. She has told us in her testimony that she had hints at dyspareunia before the surgery.

MR. SLATER: Move to strike from "but" forward.

BY MR. SLATER:

Q. You don't -- rephrase.

Do you know whether Ms. Bellew went to the emergency room because she was concerned about this sensation of something dropping into her vagina?

A. No.

Q. On June 15, 2009 Ms. Bellew saw Dr. DeHasse for the first time, right?

A. Right.

Q. And she reported that she has been feeling like she has a falling tampon. She went to see Dr. Leano who explained she has a fallen bladder. Wants surgical correction. Admits to frequency and nocturia. No incontinence. Is not

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currently sexually active. Lives at home with her daughter and grandchildren. That's what was recorded according to the record, right?

A. Did you say no incontinence?

Q. It says no incontinence right in the record. Correct?

A. Okay. But in another record I think Dr. Leano, she said she does leak with cough.

MR. SLATER: Move to strike.

BY MR. SLATER:

Q. Doctor, what I just read to you from the history -- rephrase.

What I described to you is the History of Present Illness that's documented in Dr. DeHasse's record for June 15, 2009, correct?

A. I would like to pull the record in front of me.

Q. Go ahead.

A. Okay. Disconnect for a second.

THE VIDEOGRAPHER: Sure.

Excuse me, Counselor Slater. This is Milo, the videographer.

MR. SLATER: Hi.

THE VIDEOGRAPHER: Hi. We have about ten minutes of usable tape left. Then I have to

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change.

MR. SLATER: All right. Tell me at five and at three.

THE VIDEOGRAPHER: Okay.

BY THE WITNESS:

A. I'm almost with you. Okay. And you were looking for a June visit?

BY MR. SLATER:

Q. Looking at June 15, 2009, when Ms. Bellew first went to Dr. DeHasse. Got that?

A. I am real close. I'm in June. June 20 is Leano. May 27 -- no, I don't have that page. Sorry. I mean I know I have it here somewhere.

Q. You don't have -- do you have Dr. DeHasse's records?

A. Yeah, yeah. I'm sorry. I was just having trouble getting on the same page with you.

Q. Do you have it there?

A. I'm flipping as fast as I can. I'm sorry. I know I'm using up all your tape space.

June 20, Dr. DeHasse.

MR. COMBS: June 15.

BY MR. SLATER:

Q. June 15, Dr. DeHasse.

A. You want June 15. Okay.

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Q. On June 15, 2009, when Ms. Bellew saw Dr. DeHasse, she told her she has been feeling like she has a falling tampon. Dr. Leano had explained she has a fallen bladder. That's a cystocele, correct?

A. Right.

Q. She wanted surgical correction. She admits to frequency and nocturia, no incontinence. That's what was reported, right?

A. Okay.

Q. Is not currently sexually active, lives at home with her daughter and grandchildren. That's what's reported in the history, right?

A. That's what she said.

Q. Ms. Bellew reported no pain in her pelvis or vagina when she saw Dr. DeHasse on June 15, 2009, correct?

MR. COMBS: Object to the form.

BY THE WITNESS:

A. I'm sorry. I really -- I really apologize, but I just can't find that page. So...

Q. Dr. Elser.

A. Yeah.

Q. Do you agree with me --

MR. COMBS: Adam, Adam, just here. We have

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got the page for her. So we'll give that --
THE WITNESS: Thanks.
MR. COMBS: -- to Dr. Elser.
THE WITNESS: Sorry about that. Okay.
BY MR. SLATER:
Q. Dr. Elser.
A. Yes.
Q. On June 15, 2009, when Ms. Bellew went to Dr. DeHasse, she was not complaining of pelvic or vaginal pain, correct?
A. She went to the ER last week with complaint of abdominal vaginal pain.
Q. Where does it say that?
A. History of Present Illness.
Q. Which record are you looking at? I'm looking at Dr. DeHasse's record of June 15, 2009.
A. Okay. I'm sorry. I had Dr. Leano's note.
Q. Please.
A. Okay. We're together now.
MR. SLATER: Move to strike.
BY MR. SLATER:
Q. On June 15, 2009, when Ms. Bellew went to Dr. DeHasse, she was not complaining of any pelvic or vaginal pain, correct?

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A. Correct.
Q. She said she has a sensation like she had a falling tampon, correct?
A. Right.
Q. Dr. DeHasse performed an examination, correct?
A. Yes.
Q. She found a grade 2 cystocele, right?
A. Yes.
Q. She found no evidence, according to the exam and the documentation, of any pain -- rephrase.
Dr. DeHasse found no indication on her exam of any myofascial pain or pelvic floor myalgia or hypertonicity or pelvic floor muscle spasm on that exam on June 15, 2009, correct?
A. The muscle tone is not -- is not commented on. Whether she could have had laxity at rest, whether she had hypertonicity, whether the muscles were tender or whether she could do a voluntary pelvic floor contraction.
THE VIDEOGRAPHER: Counselor Slater, we have five minutes left.
MR. SLATER: All right. Move to strike.
BY MR. SLATER:

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Q. In the exam section of this record, Dr. DeHasse does not document finding any pelvic floor muscle spasm, correct?
A. That's correct.
Q. And there are no complaints of tenderness on the exam of the vagina or pelvis, there is nothing documented, correct?
A. That's right.
Q. Based on the medical records, the only notations of spasm or pain in the pelvic floor comes after the Prolift surgery, correct?
A. Right, except I don't know what caused her pain when she went to the ER.
MR. SLATER: Move to strike after the word "right."
BY MR. SLATER:
Q. When a woman has prolapse, she can feel discomfort especially when it first happens and it can be described as discomfort, it can be described as pain, it can be described multiple ways because it's a new and troubling sensation for the woman, correct?
MR. COMBS: Object to form.
BY THE WITNESS:
A. It could be, yes.

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BY MR. SLATER:
Q. In fact, Dr. Leano wrote that Ms. Bellew had pain when she went to the emergency room but we don't know if that's Ms. Bellew's word or Dr. Leano's word, right?
A. Right.
Q. Did you look at the emergency room record to see what was described in that record?
A. I don't recall that.
MR. SLATER: All right. I think now is probably a good time if you want to get lunch. Let's go off the video and switch tapes.
MR. COMBS: Okay.
THE VIDEOGRAPHER: The time is 12:43 p.m. This is the end of Tape 1 and we are going off the video record.
(WHEREUPON, a recess was had from 12:43 to 1:25 p.m.)
THE VIDEOGRAPHER: The time is 1:25 p.m. This is the beginning of Tape 2 and we are back on the video record.
MR. SLATER: Okay.
BY MR. SLATER:
Q. I just want to establish one thing, Dr. Elser. You've worked as a consultant for

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Ethicon, correct?
A. Yes.
Q. Paid consultant?
MR. COMBS: You may have interrupted him. So if you could just answer.
BY THE WITNESS:
A. I'm sorry. Okay. I'm sorry. Did I interrupt the question?
BY MR. SLATER:
Q. I don't know. I will ask it again.
You've worked as a paid consultant for the Ethicon, correct?
A. Yes.
Q. When did you start doing that work?
I'm not going to get into a lot of detail, but I just want to establish some parameters. Let me ask it again.
When did you start working as a paid consultant with Ethicon?
A. Without knowing the exact year when we started doing TVT preceptorships.
Q. Once you began to work as a consultant with Ethicon, did you continue doing so right up until the present?
A. No, and in the way it worked was we

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would -- if they asked me to do a cadaver course, say, one November, they would give me a contract that covered up to the next 12 months and usually the topic of that contract wouldn't come up until they had another product or cadaver lab they wanted me to attend.
So, while the contracts overlapped or looked like it was continuous, it was really only event-specific.
Q. I have looked at your consulting agreements. I'm sure you've looked at them too. They initiate -- for example, I'm looking at one February 1, 2011 and it says it would continue through January 31, 2012. So, your consulting agreements would be one year at a time, correct?
A. Correct.
Q. Was there any years -- from the time you -- rephrase.
From the time you first started acting as a consultant, was there any year when you have not had a contract for that year?
A. I don't know. There might have been a 12 months in a row where I did no specific consulting. The contracts overlap that time period. And there was a time when I told them I

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would not be -- act as a consultant when I served on a committee with ACOG.
Q. When did you serve on a committee with ACOG?
A. I think it was '08 to '11. But the -- the rules changed in the middle of that, toward the end of that term with regards to relationship with industry. So, it did not cover my whole time there.
Q. What changed?
A. That committee members could not have a -- do active paid consulting with industry while they were on a committee.
So, I'm sorry, for my CV, I was on that committee 2009 to 2012. Usually --
Q. You were under contract with Ethicon during part of that time, though, as a paid consultant, correct?
A. Well, it's not like I drew a regular paycheck. That contract covered me if I accepted a one-time event on a case-by-case basis during the period of that contract. So, it was toward the end of my term on that committee that these new rules came in place. So, it applied only really for a few months at the end of that committee.

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Q. A few months in 2012?
A. Right. As far as I remember.
(WHEREUPON, there was a short interruption.)
BY MR. SLATER:
Q. So, before 2012 the ACOG rules allowed you to be a paid consultant to Ethicon, correct?
A. Correct.
Q. For example, in 2011 I have your consulting agreement here, you were a paid consultant for that year, correct?
A. I don't recall specifically, but it's very likely.
Q. You testified before the FDA on September 8, 2011, correct?
A. Yes.
Q. Did you feel that you were required to testify truthfully when you testified to the FDA?
A. Yes, I did.
Q. You told the FDA that you had no conflicts of interest to disclose, correct?
A. At that time I was not acting as a consultant to Ethicon, correct.
Q. You were under contract with Ethicon at that time as a paid consultant, weren't you?

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MR. COMBS: And, Adam, I'm just going to interject here. Tom Cartmell has fully deposed Dr. Elser on this exact issue in the --
MR. SLATER: Did he?
MR. COMBS: Yes.
MR. SLATER: Did he do a good job?
MR. COMBS: I thought so.
MR. SLATER: Okay.
THE WITNESS: He did.
MR. SLATER: I'll come back to this.
BY MR. SLATER:
Q. When you testified to the FDA regarding pelvic mesh for treatment of prolapse and all the things you told the FDA, were you telling the truth?
A. Yes.
Q. Do you agree that the FDA's view of whether or not adequate studies exist to prove the safety and effectiveness of pelvic mesh kits for prolapse like the Prolift is important?
MR. COMBS: Object to form.
BY THE WITNESS:
A. I'm sorry. Will you say that again. Does the -- did I think that the FDA thinks there needs to be more studies on safety of mesh kits?

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BY MR. SLATER:
Q. It's not what I asked you.
A. Okay.
Q. Do you agree that the FDA's viewpoint on whether there's a need for more rigorous studies regarding the safety and efficacy of mesh kits like the Prolift is important?
A. Yes.
Q. Did you ever read the 522 orders that were issued regarding the Prolift?
A. No.
Q. Actually, let me rephrase.
Did you ever read the 522 order that was issued by the FDA with regard to the Prolift?
A. I might have read part of it, but I don't remember if I read the whole thing.
Q. Do you recall anything about it?
A. I remember at least hearing about it.
Q. Well, here's my question. Do you recall actually reading the 522 order regarding the Prolift?
A. No.
Q. Do you know what it said?
A. No.
Q. Do you know what Ethicon did in response

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to the 522 order?
A. No.
Q. Do you know why Ethicon removed the Prolift from the market?
A. I don't know from Ethicon directly, no.
Q. Has anybody ever told you why the Prolift was removed from the market?
A. I can tell you that I was told it was because the cost of doing the studies was not considered, wouldn't be a good balance with the profit they could expect to make. But I don't know who I heard that from or if it was a good source.
Q. Do you know whether Ethicon tried to convince the FDA to accept studies that had already been done instead of having to do the 522 studies?
A. No. I had heard from the FDA that they were going to consider for all of the vaginal mesh kits taking studies that had already been performed into consideration at the end of a three-year period.
MR. SLATER: Move to strike.
BY MR. SLATER:
Q. Do you know whether or not Ethicon tried to convince the FDA to accept studies that had been done on the Prolift instead of having to do the 522

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studies?
MR. COMBS: Object to form.
BY THE WITNESS:
A. No.
BY MR. SLATER:
Q. So you wouldn't know what the FDA said if that proposal was made by Ethicon, correct?
A. Correct.
Q. I want to ask you if the following statement is true with regard to the Prolift:
Considering that native tissue repair is an option for many women, it makes sense to use vaginal mesh judiciously for vaginal prolapse repairs. Is that a true statement regarding the Prolift?
A. Yes.
Q. Mesh may be best for those considered high risk in whom the benefit of mesh justifies the risk of complications. Is that a true statement for the Prolift?
A. Yes.
Q. For example, women with recurrent prolapse, particularly in the anterior compartment and those of medical co-morbidities that may preclude more invasive and open or laparoscopic

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procedures, may be good candidates for vaginal mesh. Is that a true statement regarding the Prolift?
A. Yes.
Q. If you apply that criteria that we just went through to Ms. Bellew -- rephrase.
So I want to now talk to you about Ms. Bellew. She did not have recurrent prolapse when Dr. DeHasse operated on her in July 2009, correct?
A. Correct.
Q. Ms. Bellew did not have medical co-morbidities that precluded more invasive and open or laparoscopic procedures, correct?
A. I disagree. She had emphysema.
Q. You think that she had -- she was precluded from having that procedure?
A. It's a relative contraindication as is the statement that Prolift is indicated for recurrent prolapse. It was an example. It's not a strict -- it's not a strict guideline.
Q. Here's my question: Is it your testimony to a reasonable degree of medical probability that Ms. Bellew was not a candidate for an open or laparoscopic procedure to treat her

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prolapse?
A. I don't know the degree of her emphysema. It's a clinical judgment on a case-by-case basis per patient. One of the decision-making factors whether you want to put someone under general anesthetic with an endotracheal tube for a two-and-a-half to four-hour or more surgery for a laparoscopic robotic sacrocolpopexy is the presence of lung disease or other medical illnesses. So it's one of the factors to consider.
I can't say it was precluded in her. But it makes you think, oh, maybe a long abdominal surgery in the Trendelenburg position with gas and high pressure in your belly is not the best surgery for you.
Q. You're not saying to a reasonable degree of medical probability that Ms. Bellew was contraindicated to having laparoscopic or open surgery, correct?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. Correct. I'm not saying she couldn't have had it. She has risk factors for it.
BY MR. SLATER:

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Q. Ms. Bellew was a good candidate for native tissue repair, there were no contraindications, correct?
MR. COMBS: Object to the form. Asked and answered.
BY THE WITNESS:
A. Yes, but one of the considerations you take is not just could the patient tolerate the procedure, is she a candidate for it. But as you read from the other statements is high risk for recurrence.
Someone with -- who's a smoker with a chronic cough and with emphysema/lung disease is high risk for recurrent prolapse. So, a consideration would be made. Are you at high risk for failure after a native tissue repair, not can you undergo the procedure.
MR. SLATER: Move to strike from "but" forward.
BY MR. SLATER:
Q. Did you see a medical record where a pulmonary specialist or an internal medicine specialist with a focus on pulmonology diagnosed Ms. Bellew with emphysema?
A. No.

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Q. No doctor actually has diagnosed Ms. Bellew with emphysema, correct?
MR. COMBS: Object to form.
BY THE WITNESS:
A. Are you talking about before or after the Prolift surgery?
BY MR. SLATER:
Q. I'm asking you at any point. There is no doctor who has actually evaluated Ms. Bellew in order to reach a diagnosis as to whether or not she has emphysema. That has not occurred, correct?
A. I have seen emphysema in the medical records and she has been placed on oxygen at some point.
Q. The fact that some doctor may have used the word emphysema doesn't mean Ms. Bellew has a diagnosis of emphysema, correct?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. Yes, but it's most common that a doctor uses a term like emphysema when it's a diagnosis the patient has.
MR. SLATER: Move to strike from "yes" forward.
BY MR. SLATER:

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Q. You're not offering the opinion to a reasonable degree of medical probability that Ms. Bellew had emphysema, correct?
A. I would like to defer that to look through the records where we saw the diagnosis of emphysema. I don't know if she had full-blown emphysema diagnosed before the Prolift, but she is a smoker.
Q. All smokers don't have emphysema, right?
A. No, but -- but she -- it's in her records now that emphysema. So, we can --
Q. Doctor, here's my question.
A. Yeah.
Q. I read your report.
A. Yes.
Q. I'm deposing you now. I have limited time.
You have not formed the opinion to a reasonable degree of medical probability that Ms. Bellew has emphysema, correct?
A. I believe she has emphysema. I would like to look at the records with you where I saw that diagnosis.
Q. Let me ask you this question.
A. I have not read the pulmonologist

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report.
Q. Let me ask you this.
A. Yeah.
Q. What test or examination by a doctor for the purpose of diagnosing emphysema are you relying on? I never saw one. I want to know is there something that happened that I'm missing?
A. No, I have not seen a test performed, but patients aren't placed on home oxygen if they don't have lung disease.
Q. There's patients that use oxygen who do not have clinical emphysema, correct?
A. Correct.
Q. As you sit here now, because, again, I have limited time, as you sit here now, there is no clinical diagnosis by somebody who actually specializes with regard to lung diseases of emphysema in her records, correct?
A. No, I can't say that. I can look through the records to find which page the word emphysema is on so we can decide if it was a valid diagnosis or not.
Q. We can both agree the word emphysema appears in her medical records, right?
A. Yes, and can we agree that she was

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placed on oxygen because she has lung disease?
Q. Well, I don't know why she was placed on oxygen or what the thought process was or how the word lung disease is used, so I'm not going to agree to that.
Let me ask you this: You're not forming the opinion to a reasonable degree of medical probability that Ms. Bellew's history of smoking contributed or caused her Prolift-related complications, correct?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. No. Smoking is a risk factor for exposure, which we haven't seen. But we were talking about risk factors for recurrence why a Prolift might be chosen as a surgery.
MR. SLATER: Move to strike after "no."
BY MR. SLATER:
Q. Ms. Bellew's neck condition did not cause or contribute to her Prolift complications, correct?
A. No, not directly.
Q. Ms. Bellew's back condition did not cause Ms. Bellew's Prolift complications, correct?
A. I don't know.

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Q. You're not forming that opinion as you sit here now, right?
A. I think it may have contributed. I don't know.
Q. But you're not forming that opinion to a reasonable degree of medical probability. You're saying maybe but I can't say it to a reasonable degree of medical probability, correct?
A. Correct. I am not saying it caused her Prolift complications. I am saying it could be a contributing factor to her pelvic pain.
Q. Could be, could not be. You're not saying more likely than not, right?
A. Correct.
Q. With regard to her neck pain, again, you're not saying to a reasonable degree of medical probability it was the cause of the complications attributed to her Prolift, correct?
A. No, but when a patient has chronic myofascial problems in another part of the body and lower back pain and neck pain, shoulder pain, she may also have fibromyalgia which would be a contributing factor. So, I wish it had been explored more in this patient, but I can't say for sure she has it.

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Q. Let me ask you this. With regard to the neck pathology that was operated on by a surgeon, that did not cause or contribute to the Prolift complications, correct?
A. No.
MR. COMBS: Object to the form.
BY THE WITNESS:
A. Unless that's what's triggered her fibromyalgia. But other than that, no.
BY MR. SLATER:
Q. Ms. Bellew's vascular condition did not cause or contribute to her Prolift complications, correct?
A. No.
Q. Meaning I'm correct?
A. No, you're correct.
Q. I just got to watch double negatives.
Is it your opinion that Ms. Bellew had chronic fibromyalgia before the Prolift was put in her body in other parts of her body away from the pelvis?
A. I think she may have. I don't see a diagnosis of fibromyalgia being made. But I -- I would be suspicious that she has it.
Q. Have you formed an opinion to a

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reasonable degree of medical probability that Ms. Bellew had fibromyalgia somewhere in her body other than the pelvis before the Prolift was implanted or are you just saying it's possible?
A. I'm saying it's possible.
Q. The -- rephrase.
Did you see that Ms. Bellew had a mystery of migraine headaches?
A. Yes.
Q. Do you know whether Ethicon internally believed that a woman with a chronic pain condition, even migraines, would have an increased risk for pain after Prolift surgery?
MR. COMBS: Object to the form.
BY MR. SLATER:
Q. Do you know what Ethicon thought about that?
A. I'd like to look at the monograph. There might have been something about migraines in the monograph, but I don't recall specifically.
Q. If Ethicon Medical Affairs believed that women with a chronic pain condition like migraines or even fibromyalgia or anything like that could be at increased risk to develop pain after Prolift surgery, should that have been warned about in the

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IFU?
A. No, because fibromyalgia was discussed in the surgeons monograph.
Q. Do all doctors see the surgeons monograph before they use the Prolift?
A. No, but I think it's available if they -- if they want to see it.
MR. SLATER: Move to strike after "no."
BY MR. SLATER:
Q. Do you understand the purpose of the IFU under federal regulations?
A. No. I understand how it's used in -- in clinical practice.
Q. But you don't know the purpose of the IFU in terms of why it's put into the box with the product?
A. Correct.
Q. When you told the FDA that rigorous effective trials of native tissue repair comparing to vaginal mesh would be required, did you mean what you said?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. I was presenting the ACOG opinion from the committee. This was not my personal -- these

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are not my personal statements.
BY MR. SLATER:
Q. So, when you testified to the FDA to that effect, you were telling the FDA this is what ACOG thinks but you at the time did not believe that to be true. Do I understand you correctly?
A. Yes, I disagreed with that one statement.
Q. When you told the FDA eventually the best method to compare native tissue repair -- rephrase.
When you told the FDA that eventually the best method to compare native tissue repairs and vaginal mesh for prolapse is a randomized controlled trial with adequate length of follow-up and blinded assessment of outcome by independent observers, was that ACOG's position?
A. Yes.
Q. Did you agree with that position?
A. I think we talked about before the break that I would not necessarily want to compare patients to randomize them to native tissue or mesh because it's not necessarily the same group of patients in my book. I think clinical judgment plays a role.

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So, I personally disagreed with randomizing native tissue to mesh, but I agree with blinded assessment of the outcomes and long-term follow-up.

Q. And you don't believe that randomizing patients to native tissue repair and Prolift, for example, that such a study would be useful?

A. It would be interesting but it would have its limitations.

Q. So, to the extent that any such studies appear on your list, those would be studies you'd say are interesting but not something you'd rely on for your opinions. Do I understand correctly?

A. No. I think you originally asked if they were useful. Yes, they are useful. I don't think it's the end-all -- necessarily going to be the end-all-be-all study depending on the patient population studied.

Q. Do you agree with me that success rates based solely on anatomic outcomes are inadequate?

A. Yes.

Q. Do you think the Altman study published in the New England Journal of Medicine in 2011 is a reliable study?

A. Yes, I do.

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Q. Did you ever -- well, you didn't -- rephrase.

You never read Dr. Drazen's deposition, the editor of the New England Journal of Medicine, you never read that, right?

A. No.

Q. And you haven't seen any documents regarding Ethicon's input into that study?

A. No.

Q. If there is a systemic problem with the POP-Q measurements in a study that is measuring anatomic recurrences, you can't rely on the recurrence rates, correct?

MR. COMBS: Object to the form.

BY THE WITNESS:

A. It would depend on what kind of systematic problem there was.

BY MR. SLATER:

Q. How about if the people reviewing the data were finding impossible POP-Q measurements and had no way of knowing whether the possible measurements were actually accurate or not because of questions of whether or not those doing the measurements really understood the system. In that scenario would you agree that the recurrence rates

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would not be reliable?

MR. COMBS: Object to the form.

BY THE WITNESS:

A. No, I think it would depend if the errors in measurement were consistent.

BY MR. SLATER:

Q. Well, if there is an error in a POP-Q measurement and the number that is put down is not impossible, you can't always even tell that an error has been made, correct?

A. That sounds correct.

Q. So, therefore, if impossible measurements are being found and it's not just one or two isolated incidents, you have to question whether the balance of the measurements are accurate as well, right?

A. I think this is really theoretical. So, if it's a consistent error made and it's applied to all the measurements, whether it's from one site or one documenter or on both sides of the RCT, then as long as it's a consistent error, it shouldn't affect the overall outcome conclusion.

Q. When you say it's theoretical, you're saying that because you don't know that that happens in any particular study, right?

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A. Right.

Q. If there were errors in the POP-Q measurements, you would need to know more detail about the extent and have the opportunity to evaluate those measurements yourself before you could say whether or not you would trust the recurrence rates, correct?

A. Well, I might consult a statistician but, for example, if you're going to say a minus 2 measurement is always perfect and the person made a mistake, every time it was minus 2, they said zero, it's going to affect the overall end measurement but may not -- may not change our conclusions if the mistake is made consistently.

Q. Yeah, I'm not looking -- with all due respect, Doctor, I am not asking for reasons why it may be that you could ultimately decide that the numbers are okay.

This is my question: If it was brought to your attention that with regard to a particular study there were questions about the POP-Q measurements and documented errors were shown, you would want to see the measurements, you'd want to see the pattern of errors and then based on that information you would then want to form an opinion

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of whether or not you still find the recurrence rates to be reliable. Is that a true statement?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. No. I would defer it to the editors who have statisticians at their disposal to conclude whether or not the document has -- is valid to publish in their journal as well as the peer reviewers.
BY MR. SLATER:
Q. So you wouldn't want to look at the data yourself to draw your own independent opinion?
A. I don't think so.
Q. Do you consider yourself to be an expert with regard to clinical study design?
A. I've been involved in clinical study design, yes, but not -- I'm not an expert as far as statistics.
Q. Let me ask you something about the IFU. Rephrase.
Let me ask you something about the Prolift IFU. What specific information would you say actually needed to be in there to warn doctors of risks and complications? What did it need to actually say?

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A. Well, since the only thing unique about Prolift as compared to other vaginal mesh repairs or using mesh abdominally is really the introducers and the arms, I'd say then it should have information about the trocar arms, how they're placed and the mesh arms, how they are adjusted.
Q. In terms of risks and complications, do I understand you correctly that there really doesn't need to be any information in the IFU regarding risks and complications from the Prolift because you would assume doctors would just know those on their own anyway?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. Well, the -- since the Prolift -- it was recommended to be used by surgeons who are familiar with pelvic reconstructive surgery and have experience with implanting synthetic mesh, I expect risks specific to pelvic organ prolapse surgery or placement of mesh to be known to people adopting Prolift.
So, the unique things that I would want to see in the IFU before adopting are what's unique about the trocar delivery system and what's unique about the mesh arms, either to lay them, to adjust

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them and perhaps to take care of them postoperatively if there is something unusual.
Q. So, coming back to my question.
Do I understand you correctly that from your perspective the Prolift IFU did not need to list the potential risks and complications from using the Prolift? Do I understand that correctly?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. Again, I don't think you need to list every -- every risk and every complication because most of those should be known.
BY MR. SLATER:
Q. Any that you think needed to be listed?
A. Outside of what is listed or just anything in general?
Q. I want to ask -- I'm asking you if you're going to -- if you were writing the Prolift IFU, are there any risks and complications that you think would need to be listed in the IFU?
A. I would list the risks of placing the trocars, how you place them, over your finger, with the proper place to position your incision so that you can pass the trocars through the obturator space in the safest manner possible.

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Q. So, if I understand, you're saying the IFU from your perspective would need to explain how to use the trocars but you wouldn't need to list the risks or complications that could occur from Prolift surgery. Do I understand that?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. Well, what clinicians use an IFU for primarily is to understand the procedural steps if it's an unfamiliar procedure.
BY MR. SLATER:
Q. So I'm understanding you correctly, from your perspective, the Prolift IFU did not need to list any particular risks or complications, correct?
A. Unless they were unique to this device.
Q. Well, are there any that you would say are unique and needed to be included?
A. What's unique to this?
Q. That's not -- Dr. Elser, let me ask you again.
You said unless they're unique and then I asked you what do you think needed to be included and then you asked me as if I was asking a new question. So, with all due respect, let's not go

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in circles. Okay?
A. Okay.
Q. So let's do this. I'm going to come back to my question.
Are there any specific risks or complications that you think needed to be in the Prolift IFU?
A. You could talk about the risk if you make the arms too tight, if improper tensioning is used. These are things that are unique to the Prolift that would be helpful to a surgeon.
Q. And what are those risks?
A. Well, undue tension is placed on the mesh arms, I expect a higher risk of pain afterwards or fibrosis because of tension.
The thing that was unique to vaginal mesh kits outside of the obturator trocars is the full thickness dissection, which is talked about in the surgeons monograph and is talked about in the procedural videos. But placing the mesh in the proper space in the pelvis was new to using vaginal mesh that was not necessarily always done with -- with mesh that was placed without a kit before that.
MR. SLATER: Move to strike.

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BY MR. SLATER:
Q. Doctor, I'm going to try this again.
A. I'm sorry. I guess I'm not understanding what you want.
Q. I don't know. You're talking about the monograph and I'm asking you a narrow question about what needs to be in the IFU. So, I'm not really sure why we're talking about other documents. Let me try this again with you.
My question is what specific risks, not what needs to be explained about how to do the procedure. Okay. I'm not asking about what procedural information needs to be given about how to do the procedure. Okay?
A. Okay.
Q. I'm not asking about that section of describing the operation.
So now I'm asking you in the sections titled "Warnings" and "Adverse Events," what risks and complications need to be in the Prolift IFU in those sections. You've told me if the arm is too tight that can lead to too much tension and a higher risk of pain. Any other risks that need to be included in the IFU? I just want a list.
A. To be helpful to clinicians, no, because

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everything else is known to vaginal surgeons. If you are asking me what needs to be listed because of government regulations, I can't answer it.
Q. Do you know whether somebody in Ethicon Regulatory Affairs who was involved in drafting the Prolift IFU has testified that it is not legitimate to fail to warn of something based on an assumption that doctors would know it?
MR. COMBS: Object to form.
BY MR. SLATER:
Q. Are you aware of that testimony?
MR. COMBS: Object to form.
BY THE WITNESS:
A. No.
BY MR. SLATER:
Q. You noted in your report that Ms. Bellew used pain medication for her orthopedic condition, correct?
A. Yes.
Q. That's of no significance to you with regard to the Prolift injuries that are at issue in this case, correct?
MR. COMBS: Object to form.
BY THE WITNESS:
A. I mention it because my concerns are

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somebody who has chronic pain in one area is more likely to develop chronic pain in another part of the body and chronic narcotics users are often constipated and that may be underaddressed in the Prolift patient. So, chronic straining, well, it's a risk factor for recurrent prolapse and a risk factor for pelvic floor myofascial pain.
BY MR. SLATER:
Q. From your perspective, if somebody has chronic pain anywhere in their body before a Prolift, they'd be at a higher risk to develop chronic pain from the Prolift afterwards. Do I understand you correctly?
A. Yes.
Q. Is it true that you stopped using the Prolift because you were concerned about patients who were developing pain two to three years postoperatively?
A. I don't recall that. I had some patients with late onset of pain. But I had -- I had used the Prolift -- planned to use it right up until the time that it was stopped being marketed.
Q. Do you remember someone named Bart Patterson?
A. Yes, I do.

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Q. You worked closely with Bart Patterson from Ethicon professional education, correct?
A. Yes.
Q. And from time to time you would tell him about your experience with various products sold by Ethicon, right?
A. Right.
Q. And if Bart Patterson documented that you had experienced some two-to-three-year postoperative pain with some of your Prolift patients so you were currently holding off on the procedure for some of your patients, would that be accurate?
A. That sounds about right.
Q. Which types of patients did you start to hold off on using the Prolift with once you started seeing two to three years postoperative pain developing?
MR. COMBS: Object to form.
BY THE WITNESS:
A. I can't say.
BY MR. SLATER:
Q. You do agree that when you started seeing patients coming to you two to three years after their Prolifts were placed suffering from

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chronic pelvic pain, you started to exclude some of your patients as candidates for Prolift, correct?
A. I do remember talking to Bart about holding off a while while I saw how patients -- see how patients responded, how they did with treatment.
Q. And that's because you started to hold -- rephrase.
And that's because you started to exclude some of your patients from the Prolift once you started to see these postoperative chronic pain two to three years after the surgery, right?
A. Yeah, I don't remember the specific communications and I don't remember which patients I would have excluded. So, I can't tell you details.
Q. You were excluding some of your patients because you were concerned about long-term chronic pelvic pain developing after Prolift, correct?
A. I was concerned.
Q. One of your concerns was that some of those patients were developing contractions and tension banding of the mesh and dyspareunia as a result, correct?
A. If they came back with pain later, it

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was usually at the mesh arm with some contraction at the mesh arm.
Q. In fact, Ms. Bellew about two years after her Prolift surgery was found to have contraction, banding, hardening of the mesh arm leading to pain and dyspareunia which led to three excision surgeries, correct?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. Yes, she had pain at the mesh arm with fibrosis and contraction there.
BY MR. SLATER:
Q. I saw some places in your report where you talked about the risks that are unique to the Prolift and you talked about erosion and exposure, right?
A. Right.
Q. Another risk that is unique to the Prolift as compared to native tissue is mesh contraction, mesh banding, mesh hardening and all of the things that can flow from that, correct?
A. Contraction around the mesh, right. But we can see fibrotic scar banding with native tissue repairs.
Q. If you see -- rephrase from "but"

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forward.
When there is fibrosis and fibrotic bridging and contraction of the mesh, that does not soften over time. That remains hard and continues to progress in many women. Correct?
MR. COMBS: Object to form.
BY THE WITNESS:
A. No.
BY MR. SLATER:
Q. Are you familiar with what Ethicon thinks about that question, the people in that company that have actually studied this subject?
A. They may have studied a lot of things in the lab. I can explain how I feel it affects our patients.
Q. Let me ask you this: Are you aware of whether Ethicon is constantly in communication with doctors and surgeons not only in the United States but around the world about their products including Prolift?
A. I'm not aware to the extent, no. I imagine they are in contact with physicians who use the products.
Q. You made no effort to learn what Ethicon Medical Affairs knew from its outreach to doctors

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around the world about the Prolift and the extent of complications, correct?
A. Correct.
Q. When a woman has scarring after a native tissue repair, that will usually soften and resolve over the course of time, correct?
A. Not necessarily.
Q. I didn't say in all cases, but for the most part it will, right?
A. It depends on what it -- when it's presenting.
Q. The majority of the time that a woman has some scarring and discomfort from that scarring after native tissue repair, that will resolve over time as the scar softens, correct?
A. No. Again, it depends when it presents. If it's for six-week postoperative check and she has pain and scarring, yes, that's likely going to soften up with time. If she comes back a year or more after her surgery with a scar band that's a very taut, contracted scar band, whether it's around a suture or not, that may not soften up.
Q. That would be very rare after a native tissue surgery, right?
A. I don't think it's very rare.

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Q. Do you have any statistics or data you can point to on that?
A. We can talk about risk of -- new onset of pain after native tissue repairs.
Q. I'm talking about the specific issue --
A. Specifically scar banding?
Q. I'm talking about somebody having what you called a scar band after native tissue repair more than a year after the surgery. That would be rare, correct?
A. It's -- most patients don't get it. I wouldn't call it rare. We certainly see it on a regular basis in our urogynecology practice.
Q. If Ms. Bellew had had an alternative procedure like native tissue repair with suture, you can't say that she would have suffered any particular complications from that. That would be speculative. Correct?
MR. COMBS: Object to form.
BY THE WITNESS:
A. Yes.
BY MR. SLATER:
Q. It's my understanding that you believe Ms. Bellew has myofascial pain from pelvic floor myalgia, correct?

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A. Correct.
Q. And you believe that it would be appropriate for her to have physical therapy for the pelvic floor and a dilator and other treatment to try to resolve that or to make that better, correct?
A. I think physical therapy, pelvic floor physical therapy, yes, absolutely. Possibly she'd benefit from a dilator.
Q. Pelvic floor physical therapy is invasive, correct?
A. Usually.
Q. Pelvic floor physical therapy is not successful in all women in completely resolving their myofascial pain in their pelvic floor. In fact, usually with somebody who has chronic pelvic floor myalgia, at best it will just help to reduce the pain, correct?
A. I don't know if I agree. It depends on the quality of the physical therapist and the patient's willingness to perform her exercises on a regular basis. But we see for the majority great success with pelvic floor physical therapy.
Q. Is there any study you can point to that actually studied the question of the success of

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pelvic floor physical therapy in a woman with chronic pelvic floor myalgia?
A. No, there is not. There is a paucity of that data in our literature. So I'm relying on clinical experience.
Q. Whether or not Ms. Bellew used estrogen in her vagina had nothing to do with her developing contractions and fibrosis of the mesh itself, correct?
A. No, not necessarily. Estrogen does promote healing and a thin post-menopausal vaginal epithelium is more likely to sclerose and fibrose.
Q. Well, the sclerosis and fibrosis of the mesh occurred behind the vaginal wall, not in the vaginal wall, correct?
MR. COMBS: Object to form.
BY THE WITNESS:
A. I don't think so. I think in her case, because it's being described by Dr. DeHasse as a split thickness dissection, that it was placed in the wall of the vagina, not behind it.
BY MR. SLATER:
Q. You believe what was placed in the wall of the vagina?
A. The mesh.

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Q. You don't believe there was a full thickness dissection?
A. I don't.
Q. Is that opinion in your report?
A. I believe it is.
Q. From what you read in the procedure and Dr. DeHasse's deposition, did she know about the need for a full thickness dissection after taking Ethicon's professional education course?
A. I don't know what she knew about, but she testified in her deposition that she performed a split thickness dissection.
Q. Did she say that for the entire Prolift or was she talking about the hysterectomy?
A. It would be for the Prolift portion.
Q. The full thickness dissection is performed in order to reduce the risk of mesh exposure into the vagina, correct?
A. Yes, but I believe it also helps prevent the scarring and fibrosis. If you have got a mesh embedded in the skin, it's more likely to be stuck in its position.
MR. SLATER: Move to strike after "yes."
BY MR. SLATER:
Q. Is there any document whatsoever that

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you can point to anywhere in the world that says that the reason for the full thickness dissection is to in any way impact on the risk of having contraction or fibrotic bridging on the mesh?
A. No, this is my clinical experience.
Q. And are there patients you've seen where you believe there was not a full thickness dissection and they had mesh contraction that you attributed to the type of dissection, that's something you're saying you've seen in your experience?
A. Yes.
Q. How many times?
A. Several. When we first used self-cut mesh to put in the vagina, we were not doing full thickness dissection. It was not until more experience and experiencing the fibrosis and the extrusions at multiple sites from trying to put mesh in a split thickness dissection that we learned a better position was in the true paravesical space behind the full thickness epithelium.
Q. The full thickness dissection is contrary to the training and education of many physicians who were trained to do split thickness

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dissections, correct?
A. They were trained to do split thickness native tissue repairs.
Q. Right. And to a large -- rephrase.
And it's fair to say that the full thickness dissection is counterintuitive to many physicians, correct?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. It may be counterintuitive, but then mesh may also be counterintuitive.
BY MR. SLATER:
Q. Is the answer to my question yes, that the full thickness dissection is counterintuitive to many physicians?
MR. COMBS: Object to form.
BY THE WITNESS:
A. Yes. For a general Ob-Gyn who trained in a program where only native tissue repairs were performed, they likely only learned split thickness repairs, which applies only to native tissue repair.
BY MR. SLATER:
Q. You cannot say whether or not -- rephrase.

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You would agree with me it's more likely than not that Ms. Bellew still would have had contractions, fibrosis and hardening of the mesh regardless of which type of dissection was performed here, correct?
A. No, I can't say that.
Q. Do you have an opinion one way or the other or you're just saying it's possible it could have happened, possible it wouldn't have; speculative but it's possible?
MR. COMBS: Object to form.
BY THE WITNESS:
A. I think it's very likely that if you put the mesh in a split thickness in the wall of the epithelium, you're causing fibrosis, more likely to cause scarring.
BY MR. SLATER:
Q. It would be speculative what -- to say what would have happened if a full thickness dissection was done as you've said?
MR. COMBS: Object.
BY MR. SLATER:
Q. Is that fair?
MR. COMBS: Object to form.
BY THE WITNESS:

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A. Yes.
BY MR. SLATER:
Q. Yes?
A. Yes.
Q. I'm not -- just so you know, I'm not badgering you. Just sometimes the sound, I can't tell what you're saying.
A. Oh, you didn't sound like you were badgering me that time.
Q. I try to be clear when I am badgering.
A. Okay.
Q. When I'm badgering you, Mr. Combs turns red in the face.
A. I'm not supposed to look at him.
Q. Well, you will see the room glow if I'm doing my job.
Let me ask you this. I think we might have touched on it earlier. I just want to be sure.
Do you have an opinion based on any particular study of documents or any other information as to the size of the mesh pores in the Prolift when it's actually put into the body?
A. No.
Q. On page -- do you have your report

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handy?
A. I should.
Q. Look at page 12, please. Tell me when you're on page 12?
A. I'm there.
Q. On page 12 you cite to an article by Fatton, F-a-t-t-o-n, and some members of the TVM group regarding the Prolift, right?
A. Right.
Q. You cite some statistics that were reported, some data from that study, correct?
A. Right.
Q. Do you think it's important that when you cited data from a study in your report that you were evenhanded and cited the data that may be good or may be bad or vice versa?
Let me ask it differently.
Do you think it was important when you cited data in your report to be fair and balanced in how you did it to give a full view of the important data?
A. I pulled up data that I recalled that I thought was important to know about Prolift. I wasn't looking for an equal amount of bad data or good data.

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Q. Well, you took some data from a table that gave three-month data. What you didn't cite from that table was the 17% shrinkage rate. You didn't cite that in your report, correct?
A. Correct.
Q. You knew about the 17% shrinkage rate, correct?
A. I read about the 17% shrinkage rate and I've always found it difficult to imagine how they measured it.
Q. Are you saying that you don't believe that Jacquetin and Fatton and Cosson and the French TVM group could credibly document the shrinkage for their patients from the Prolift procedure that they created?
A. No, I think these are very good researchers and they certainly know the product and have the most experience. I'm just never sure how to apply that kind of information clinically to my patients.
Q. Did you make a conscious decision not to include the 17% shrinkage rate that was found in that study?
A. No, I don't recall having that conversation with myself. It never came up should

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I include this or not. I looked at the information I thought was pertinent.
Q. You would agree that the 17% shrinkage rate at three months is significant, correct?
A. I don't know.
Q. In this case where mesh shrinkage/contraction is the complication that was suffered by Ms. Bellew, wouldn't the 17% shrinkage rate found at three months by the inventors of the Prolift be of significance?
MR. COMBS: Object to form.
BY THE WITNESS:
A. No.
BY MR. SLATER:
Q. Are you aware of any clinical data reported by the French TVM group regarding the percentage of women treated with Prolift suffering from painful mesh contraction due to the Prolift?
A. I'm sure I have it. I don't have it at the tip of my brain now.
Q. It's not cited anywhere in your report, correct?
A. Right.
Q. Are you familiar with the study authored by Velemir, Fatton, Jacquetin regarding ultrasound

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and tracking retraction of Prolift mesh?
A. No.
Q. On page 14 of your report you cite the Altman RCT from 2011 and you indicate that the patients who returned to surgery to treat mesh exposure was 3.2% of the patients, right?
A. Correct.
Q. There is no information in that article about the total erosion or exposure rate. They just tell the percentage that went back for surgery, right?
A. That's right.
Q. And they don't define surgery so you don't know if someone getting an operative procedure in an office versus a hospital was counted. We don't know that, right?
A. Right. We don't know if it was or was not.
Q. The Withagen study from 2011 you cited just below that on page 14. They found about 17% of the patients had mesh exposure, right, into the vagina?
A. Right.
Q. I'd like you to assume that there are -- rephrase.

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I'm going to talk to you about the Blandon article in the abstract a little bit with you. Okay?
A. Okay.
Q. I'd like you to assume for this question that Ethicon knew that there were doctors who would use the Prolift who would not have known that the very serious complications described in that article were potential risks with the Prolift, and I'd like you to assume Ethicon knew those risks as of the date the Prolift first went on the market. Okay?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. Okay.
Q. Do you understand my hypothetical?
A. Yeah.
Q. Assuming my hypothetical to be true, would you agree that those risks described in the Blandon article should have been disclosed in the IFU? Yes or no.
A. That patients may have mesh exposures, contractions that require more than one surgery to fix?
Q. The full scope of complications

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described in that article, the very severe complications described.
MR. COMBS: Object to form.
BY THE WITNESS:
A. I would say, then, it depends on the rate. If it's a rare complication or not, it's hard to say how much information needs to go in the IFU.
BY MR. SLATER:
Q. So you can't form an opinion on that one way or another or you're saying -- rephrase.
So, you're saying that information would need to be in the IFU if Ethicon knew it and knew it was going to happen to some women from the Prolift. Would you agree with that?
MR. COMBS: Object to form.
BY THE WITNESS:
A. Again, I think I would not expect to read in an IFU every rare complication. It depends how much of a problem it's going to be clinically.
BY MR. SLATER:
Q. Well, you don't know what the rate of the most severe life-changing complications from the Prolift is. You don't have that data, right?
MR. COMBS: Object to form.

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BY THE WITNESS:
A. Correct.
BY MR. SLATER:
Q. If Ethicon knew that those very severe complications described in the Blandon article were going to happen to some patients due to the Prolift, they knew that, and they knew that would not be known by all of the doctors using the Prolift, would you agree with me in that circumstance that those risks of those very severe complications should have been disclosed in the IFU?
A. No. And, again, because the IFU is not the only document we rely on and even the surgeons starting to use Prolift were -- were advised to be familiar with pelvic reconstructive surgery and use of permanent implants.
So, I would expect that people using Prolift would know something about complications implanting mesh.
MR. SLATER: Move to strike after "no."
MR. COMBS: Adam, we have been going for over an hour now. Sometime in the next five minutes let's take a break.
MR. SLATER: We can take a break right now.

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MR. COMBS: Okay.
THE VIDEOGRAPHER: The time is 2:26 p.m. We are going off the video record.
(WHEREUPON, a recess was had from 2:26 to 2:41 p.m.)
THE VIDEOGRAPHER: The time is 2:41 p.m. and we are back on the video record.
BY MR. SLATER:
Q. Okay. Doctor, do I understand your testimony to be if there is something that Ethicon needed to tell surgeons about risks and complications about the Prolift and Ethicon failed to do so in the IFU, that's okay as long as they gave that information in the surgeons monograph?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. It's hard for me to answer that because you said if it's something that they need to tell surgeons. And that --
Q. That's right because you only thought there was thing they needed to tell --
A. Well, it's a bit subjective but the monograph was --
Q. Let's talk about the monograph.
A. Okay.

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Q. Do you know whether all the information in this monograph is true?
A. I don't know. I'd be happy to go through it with you.
Q. I don't want to go through it with you. I want to ask you. You're the expert. You listed this in your report and you've told me it's one of the few documents you're relying on.
So, I'm asking you. Is all the information in the monograph true?
A. I can't say it's all true. Certainly some of it's going to be opinion that's going to vary among surgeons. But largely it's a good place for surgeons to get information about this procedure.
Q. Do you know what Ethicon Medical Affairs thought as to whether or not most doctors understood the tension-free concept in connection with the Prolift?
A. No.
Q. And you don't know whether most doctors understood it or not, right?
A. Correct.
Q. You would agree that if the tension-free concept was not understood and mesh ended up under

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tension after closure of the incisions, that could increase the risk for complications, right?
A. Yes.
Q. You would also agree that even a doctor who is fully trained, follows the Prolift technique down to the T, can end up with tension on the mesh that can lead to complications, correct?
A. Yes.
Q. Is it your opinion that the surgeons monograph can be a substitute for the IFU in providing information about risks and complications to physicians?
A. In clinical use, yes.
Q. In terms of how the medical device company Ethicon is supposed to operate in the real world in providing information to doctors, was Ethicon allowed to provide information in a source other than the IFU even if that information belonged in the IFU?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. I don't know what they're allowed to do or supposed to do or what -- what federal rules or regulatory guidance applies. I know how surgeons get their information and it's not typically that

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the IFU is their one and only go-to source. They would look to literature, experience, colleagues, monographs.
BY MR. SLATER:
Q. Well, that's just the doctors you've spoken to and that you know, right?
A. I can't know what every other doctor does, but I have interacted with doctors at all levels, in teaching institutions, at the preceptorships.
Q. How many doctors have you spoken to about whether or not they read and rely on the IFU to tell them the risks or complications with a mesh kit? How many doctors have you had that specific conversation with?
A. I may not have had that exact conversation. But I know from the preceptorships, interacting with dozens of surgeons wanting to bring vaginal mesh into their practice or specifically the Prolift into their practice, their main concern with IFU was procedural steps. This was not the document they looked to for complications.
MR. SLATER: Move to strike from "but" forward.

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BY MR. SLATER:
Q. Have you ever asked another doctor, "Do you look to the IFU to learn what the risks and complications of this procedure are" with regard to any particular kit? Have you ever asked a doctor that question?
A. No.
Q. You would agree with me that there is not data establishing that the use of topical estrogen has any true impact on whether or not a woman will have complications with the Prolift, correct?
MR. COMBS: Object to form.
BY THE WITNESS:
A. Correct.
BY MR. SLATER:
Q. And you cannot say that if Ms. Bellew had used estrogen either more often or in different quantities that that would have prevented any of her complications, correct?
A. No, we can't say for sure in this case, but we know that estrogen does seem to promote wound healing.
Q. You can't say that the use of estrogen would have had any impact on the complications that

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Ms. Bellew had with the Prolift. That would be speculation, correct?
A. Right. We cannot say for sure.
Q. It would be speculative, correct?
A. Yes, but the -- we believe it's such an important factor, we counsel our patients, we don't know for sure if you will heal better with estrogen but we advise you to use it to help prevent your chances from getting a complication.
Q. Doctors tell patients to use the estrogen, but it's not been established that it actually helps to prevent Prolift complications, correct?
A. I don't know of it being studied specifically preventing mesh complications.
Q. Nothing you can point to, right?
A. Correct.
Q. I went through the -- let me ask you this: If Ethicon knew that in some women they could have Prolift complications, the women could go through multiple operations, and despite that, the complications could not be safely and effectively treated and the woman would be left with permanent and chronic pain, if Ethicon knew that, should they have warned about that in the

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Prolift IFU?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. Again, I don't know that the complications need to be spelled out in the IFU from a clinical point of view.
BY MR. SLATER:
Q. Just asking about that complication. What I just described, if Ethicon knew that, should they have warned about it in the IFU?
A. No. Again, the IFU is more important clinically as a procedural guidance and there is other -- there is other areas where physicians get their information about the complications.
Q. I think I understand you now. Let me ask you this. Tell me if I'm correct.
A. Okay.
Q. From your perspective the IFU is a source of information for doctors as to how to do the procedure. There are other places that doctors should go if they want to learn about the risks and complications of the procedure. Do I understand you?
A. Yeah, there's other places they go. They rely on their experience, they rely on

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colleagues, they rely on conferences, literature. There's much more goes into it than the IFU stating --
Q. So, from your perspective, from your perspective in your opinion, the purpose of the IFU is not to provide the risks and complications known to Ethicon regarding the Prolift to physicians. That's your perspective and your opinion, correct?
A. That's my opinion and the Instructions for Use, how do I use this in the OR. That is how it's going -- I believe will be accepted by most surgeons. And you just gave me -- I want to do this study now. I'm going to survey all kinds of gynecologic surgeons to see if they even know what an IFU is.
MR. SLATER: Move to strike from "that" forward.
BY MR. SLATER:
Q. Let me ask you this. If Ethicon knew that some women would suffer complications from the Prolift that would be severe and that despite multiple operations the woman could not be safely and effectively treated and would be left with permanent chronic pain, if Ethicon knew that, would you agree with me they needed to get that

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information to physicians in some form, whether through the IFU or some other document from Ethicon, they needed to get that information to doctors?
MR. COMBS: Object to form.
BY THE WITNESS:
A. Yes, we would like to have that information.
BY MR. SLATER:
Q. With regard to all of the very serious complications described in the Blandon article, would you agree to the same thing, that Ethicon needed to get that information to doctors in some form if they knew those were going -- were risks with the Prolift?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. Well, I think that long list of complications, some are not specific to Prolift. There are complications of vaginal surgery, vaginal mesh.
BY MR. SLATER:
Q. My question is if Ethicon Medical Affairs has admitted that they knew that all of those complications described in that article were

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risks with the Prolift, if they knew that, would you agree they needed to get that information out to surgeons, whether in the IFU or some other document, so it would be available to doctors?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. Again, I think physicians need to understand the risk of surgery they're undertaking, whether they are looking to the company to provide that information or the literature, there is other sources.
MR. SLATER: Move to strike.
BY MR. SLATER:
Q. My question is what the company needed to do in your opinion. Do you agree that Ethicon, if they had that information, needed to get that out to surgeons either in the IFU or some other document so that they would get that out to doctors? Do you agree with that?
A. Yes, with the caveat that this information is -- was frequently already out there in the literature known to physicians. It's hard to know when it's the company's job to say, hey, do you know you can get a wound infection after you make a wound. A lot of this --

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MR. SLATER: Move to -- move to strike after the word "yes."
BY MR. SLATER:
Q. In essence your opinions about what Ethicon needed to warn doctors about is not with reference to any standards that actually exist in the medical device world about what Ethicon was required to do. You're just talking about subjectively what you think the rules should be. Correct?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. Yes, I don't know what the regulatory obligation of the company to notify surgeons is, when the complication is serious enough or when it's common enough.
But as a clinician who wants to know about complications that are unique to a device, I want that communicated in some way.
Now, if Ethicon has a laparoscopic trocar and we find out you can put it in someone's bellybutton and hit the aorta, is that something the company needs to call and tell us about or put in the IFU when it's a known risk of placing a sharp instrument in the belly? It's a very serious

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complication.
MR. SLATER: Move to strike from "now" forward.
BY MR. SLATER:
Q. When you give the opinion that the IFU adequately warned surgeons of the potential risks with the Prolift, which is the opinion in your report, correct?
A. Correct.
Q. You're basing that opinion on your foundational opinion that the IFU is not a place where Ethicon was required to provide information about risks and complications of the Prolift, correct?
MR. COMBS: Object to form.
BY THE WITNESS:
A. They do warn of risks and complications in the IFU.
BY MR. SLATER:
Q. That's not what I'm asking you.
A. Then can you ask me again.
Q. Is it your opinion that since Ethicon didn't needed to provide information about risks and complications in the IFU, whatever they provided was adequate because they didn't need to

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provide that information to begin with?
MR. COMBS: Object to form.
BY THE WITNESS:
A. They are -- I guess I need to ask you a clarifying question.
If -- if there is an IFU out there and a complication gets reported, does it now need to get put into the IFU?
BY MR. SLATER:
Q. You're asking me that question?
A. Yeah. I'm asking if that's what you're asking me.
Q. You don't know -- that's not what I'm asking you. You don't know the answer to that question, do you? The one you just asked me you're asking because you don't know, right?
A. Oh, I'm not doing your job.
No, I want -- I want to know if that's what you're asking me. Are you talking about getting it into the IFU that's already out there or just the IFU from Day One?
Q. Well, first of all, now that you ask me to clarify, first of all, from Day One.
Is it your opinion the IFU adequately warned of the potential risks with the Prolift

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since from your perspective Ethicon didn't need to warn of any risks anyway so whatever they put in there is more than they needed to do anyway?
MR. COMBS: Object to the form.
BY MR. SLATER:
Q. Do I understand you?
A. Yeah, and they did have warnings about the complications.
Q. Do I understand -- so I understand your opinion, correct?
A. Correct.
Q. I'm going to ask you a different question now relating back to what you asked me.
Once the IFU is out there, if Ethicon learned of a risk or a complication that was not previously warned about and it was a significant risk or complication in terms of the harm it could cause to a woman, do you know whether or not Ethicon had any obligation or have any opinion whether they had any obligation to get that information out to doctors?
A. I don't know what the obligations are. So, do they get -- would it be updated on a regular time interval or is it depending on when complications happen?

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Q. Again, in forming your opinions, you don't know what Ethicon's obligations were to warn, correct?
A. Correct.
Q. So, your opinions are not based on what Ethicon was obligated to do from any source, right?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. I -- my opinion is that as a surgeon who has -- who does pelvic reconstructive surgery and using mesh that what I expect the company put in the IFU to help me understand how to do pelvic reconstructive surgery with mesh may not include every single complication.
MR. SLATER: Move to strike.
BY MR. SLATER:
Q. All I'm saying is the opinions you're offering about the warnings are not based on any standard whatsoever as to what Ethicon was required to do because you don't know what they were required to do, right?
A. No, I'm commenting on what the average pelvic surgeon needs to know.
MR. SLATER: Move to strike.
BY MR. SLATER:

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Q. Is the answer to my question yes?
MR. COMBS: Object to form.
BY THE WITNESS:
A. Yes.
BY MR. SLATER:
Q. I'd like you to assume -- no, I'll withdraw that. Just give me one second. I'm almost done.
I didn't finish with your materials in your report. Let's go to the end of your report, the last two pages.
The second-to-last page of your report of Attachment B is a list of expert reports, depositions, other and medical records.
Do you see that?
A. Yes.
Q. With regards to those categories of documents, that's all you saw. And, of course, the medical records go over to the next page. You didn't see any other expert reports, depositions or medical records, correct?
A. I have since seen some more depositions and expert reports.
Q. Did you read or rely on any of those depositions or expert reports?

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A. Not for this report, no, because I read those afterwards.
Q. What I'm asking you is as you sit here now, are you relying on any other depositions or expert reports other than what's listed here for your opinions?
A. No, I don't think so.
MR. SLATER: Hey, Phil.
MR. COMBS: Yes.
MR. SLATER: I know that a Deposition Notice was served. My guess is your position is you will respond to it in due course but not today?
MR. COMBS: Yeah, that's correct, Adam. And we have brought the materials that Dr. Elser had that would be responsive. But I'll tell you, other than the case-specific stuff, it's the same stuff that she brought when Tom Cartmell deposed her in Edwards. You all have got it all.
Absolutely we are going to forward to you the invoices and billing records. I asked Dr. Elser this morning if she had prepared a bill in Bellew. She hadn't. If you want to ask her what the approximate total is going to be, please feel free to do so. But we obviously will provide that to you.

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MR. SLATER: Let me tell you what I'd like to do. To the extent the medical records are listed in the expert report, I don't need to mark those. To the extent -- I know that the article that was mentioned earlier I'm going to need that and I guess we forgot about it. But you can -- I'd like to have that sent over to me.
MR. COMBS: Yes.
MR. SLATER: Do we know the title of it now?
MR. COMBS: Let's go ahead -- let's go off the record just for a second off the video. Let's you and I talk and we will assemble that.
THE VIDEOGRAPHER: The time is 3:02 p.m. and we are going off the video record.
(WHEREUPON, discussion was had off the record.)
THE VIDEOGRAPHER: The time is 3:05 and we are back on the video record.
(WHEREUPON, a certain document was marked Elser Deposition Exhibit No. 2, article, "Myofascial Pelvic Pain" by Spitznagle and Robinson, for identification, as of 09/16/2014.)
BY MR. SLATER:

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Q. Doctor, we've marked as Exhibit Elser 2 the article that you had mentioned to me earlier as being in addition to what was on your -- listed in your report. Can you just read the title of it real quick?
A. It's called "Myofascial Pelvic Pain" and the authors are Spitznagle and Robinson who are both doctors of physical therapy and it was in Ob-Gyn Clinics of North America published in 2014.
Q. March 14, this year?
A. In 2014. I don't have a month on it.
Q. Is that article of some significance to you?
A. Oh, it talks about different treatments for myofascial pelvic pain, including defining it and what some symptoms might be and how to treat it.
Q. Myofascial -- rephrase.
Myofascial pelvic pain like Ms. Bellew has in your opinion can be treated with the types of treatments described in that article and in some women it will not resolve and remain a permanent condition, right?
A. It can remain a chronic condition, yes.
Q. Now, can you give us -- I know that

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you're going to produce your invoices through counsel to us and we just talked about that off the video record.
But can you just give me the best estimate you can of the amount of time you've spent on this case and the amount of billing?
A. It will likely be between 100 to 130 hours.
Q. And what's your billing rate again?
A. 600 for the review and meetings and -- I mean, 500 an hour and then 600 an hour for today.
Q. With regard to what was requested in this Deposition Notice, it's my understanding that you have with you obviously the article we just marked, copies of the medical records listed in the report, and anything else you have with you is listed in the report already, correct?
A. I believe so.
Q. And we already went through at the beginning of the deposition and even recently when you talked about the recent materials, you've already told me what it is you actually relied on to form your opinions in this case, correct?
A. Yes.
MR. SLATER: I don't have any other questions.

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MR. COMBS: Adam, we are going to have some redirect. It won't be extensive. Let's take about a ten-minute break and then we'll come on and do that.
MR. SLATER: Splendid.
THE VIDEOGRAPHER: The time is 3:07 p.m. and we are going off the video record.
(WHEREUPON, a recess was had from 3:07 to 3:29 p.m.)
THE VIDEOGRAPHER: The time is 3:29 p.m. and we are back on the video record.
EXAMINATION
BY MR. COMBS:
Q. Dr. Elser, I'm going to ask you some questions now.
Do you remember the questions that Mr. Slater asked you regarding Ms. Bellew and whether she presented with dyspareunia?
A. Yes.
Q. Now, in her deposition did Ms. Bellew discuss presentation of dyspareunia prior to the Prolift implantation?
A. At her deposition she was asked if she talked with anyone about the upcoming surgery. This was the initial implant surgery. And she said

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she talked it over with her long-term boyfriend, and the main thing they talked about was how long it would be before she could have sex again and that was an important issue because they had not been able to have sex because it hurt.
Q. Now, Dr. Elser, have you conducted surveys related to baseline dyspareunia rates of the patients that present to you for urogynecological treatment?
A. Yes, in 2009 I presented an abstract on baseline sexual function of women presenting with urogynecologic problems to our clinic. So, it was all -- we took all new patients over a 12-month period. And the baseline dyspareunia rate was 37 percent.
Q. And that was of the patients that presented to you that -- that calendar year for urogynecological treatment?
A. Right. That's all the new patients that I saw in a calendar year.
Q. Dr. Elser, Mr. Slater asked you numerous questions about the IFU. You are not an expert in regulatory affairs, are you?
A. No.
Q. You're not an expert in government

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regulations, are you?
A. No.
Q. And is your opinion regarding the IFU based upon how an IFU is used by clinicians?
A. Yes. My interactions with clinicians for a variety of procedures, at preceptorships, at training residents, learning new procedures in the OR.
Q. And have you reviewed the IFU that was in place for Prolift at the time of Ms. Bellew's surgery?
A. Yes, I have.
MR. COMBS: And we'll mark that as Elser Exhibit 3.
(WHEREUPON, a certain document was marked Elser Deposition Exhibit No. 3, Gynecare Prolift IFU; Bates Nos. ETH.MESH.02341454 - 02341459 for identification.)
BY MR. COMBS:
Q. And, Dr. Elser, is it your opinion that this IFU adequately conveyed the risks to surgeons that were using the Prolift system?
MR. SLATER: Objection.
BY THE WITNESS:

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A. So, this Prolift IFU has the list of contraindications, warnings, precautions and adverse reactions. And these were adequate, included, carefully placing it to avoid damage to vessels, nerves, bladder, bowel, what the patient should avoid postoperatively, avoid placing excess tension on the mesh implant during handling.
BY MR. COMBS:
Q. And during your testimony did you talk several times about the fact that the IFU makes a reference to surgeons that are implanting the Prolift device should be surgeons who have used this type of procedure before?
A. Yes.
MR. SLATER: Objection.
BY MR. COMBS:
Q. And does the IFU also make it clear on the first page of it that training is recommended and available for Prolift?
A. Yes, it does.
MR. SLATER: Objection.
BY MR. COMBS:
Q. And did you participate in that prof ed training?
A. Yes, I did.

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Q. Now, is your opinion based upon the adequacy of the IFU based upon other things in addition to the review of the IFU?
MR. SLATER: Objection.
BY THE WITNESS:
A. Yes, because the training was offered. It was offered with -- in a didactic cadaver lab to go see someone with more experience use the product for the first time and to have a surgeon come to the hospital to be there to observe the first few cases.
BY MR. COMBS:
Q. And have you had -- well, strike that.
Is your opinion regarding the risk information that was conveyed to surgeons also based upon your review of the clinical literature?
A. Yes.
MR. SLATER: Objection.
BY MR. COMBS:
Q. Is it also based upon your membership in professional societies?
MR. SLATER: Objection.
BY THE WITNESS:
A. Yes.
BY MR. COMBS:

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Q. And is it also based upon your interaction with other physicians?
MR. SLATER: Objection.
BY THE WITNESS:
A. Yes.
BY MR. COMBS:
Q. And can you explain to the Court or to the jury, when you say that, what interaction are you talking about?
A. Well, there is not only interactions with other members of societies like AUGS, SGS, IUGA, but after the preceptorships, both when I went as a student learning the procedure and as a preceptor, the information of the trainer's contact info was provided and freely encouraged anyone who had received training, call us at any time. Call if you have question about a patient's post-op course, about if you should decide which patient to implant this on. We as preceptors now are available to you.
That was not -- there was no clock running with you're getting paid for that. This was something we were happy to do to help other physicians understand how to use mesh to best take care of patients and how to manage any problems.

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Q. And have you used IFUs in your clinical practice?
A. I have.
Q. And was it your testimony that you read this IFU at the time that it came out and that when you were using the Prolift device?
A. Yes.
MR. SLATER: Objection.
BY MR. COMBS:
Q. You talked earlier about what are some of the complications that are set forth in the IFU?
A. It does talk about adverse reactions. So, typically associated with surgical implantable materials, infection potentiation, inflammation, adhesion, fistula, erosion, extrusion and scarring that results in implant contraction, besides injury to vessels, nerves, bladder, urethra or bowel.
Q. Now, Dr. Elser, can any of the conditions that are set forth in this IFU lead to the development of dyspareunia?
MR. SLATER: Objection.
BY THE WITNESS:
A. Yes.
BY MR. COMBS:
Q. And is that a fact that would be known

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to pelvic floor surgeons?
A. Yes.
MR. SLATER: Objection.
BY THE WITNESS:
A. Dyspareunia after pelvic surgery would be known to pelvic floor surgeons.
BY MR. COMBS:
Q. And, in fact, that's a risk of any pelvic floor surgery, isn't it?
MR. SLATER: Objection.
BY THE WITNESS:
A. That would be a risk of any pelvic floor surgery.
BY MR. COMBS:
Q. And that would be -- that would be a fact that would be known by any surgeon who was doing pelvic floor reconstructive surgery, wouldn't it?
A. Yes.
MR. SLATER: Objection.
BY MR. COMBS:
Q. Now, Dr. Elser, have you had occasion to talk with other surgeons regarding the Prolift IFU?
MR. SLATER: Objection.
BY THE WITNESS:

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A. I have.
BY MR. COMBS:
Q. And can you tell us what situations that arose in?
A. For the most part it would be at the preceptorships, people attending, learning how to do the procedure, would have a lot of questions about the procedural steps. I want to take an IFU with me for maybe I'm not going to do my first case until a couple months after training to remember the procedural steps.
But in follow-up in many courses and cadaver labs, I've never heard a surgeon say, "Boy, I wish I hadn't use that product" -- "I wish this would have been in the IFU. If I had read this particular complication in the IFU I never would have used a product," I have never heard as a criticism of the IFU.
Q. When you're talking about criticism in the IFU, are you talking about the Prolift IFU?
A. Yes.
MR. SLATER: Objection.
BY MR. COMBS:
Q. Now, you've told us briefly but what are the other sources of information by which surgeons

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learn risks?
MR. SLATER: Objection.
BY THE WITNESS:
A. It's going to be in training, whether that's residency, fellowship training, in practice, and speaking with colleagues and reading the literature, attending conferences and presentations.
BY MR. COMBS:
Q. Do you have any firsthand knowledge of Ethicon's professional education that was offered to supplement surgeons training with Prolift?
MR. SLATER: Objection.
BY THE WITNESS:
A. There were slide decks and reps would -- always had slide decks to hand out or videos. Monograph was available. The Instructions for Use were available, brochures were available and reproductions of any literature that was relative -- relevant.
BY MR. COMBS:
Q. And as you testified earlier, is the monograph that you're referring to the Surgeons' Resource Monograph?
A. Yes.

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Q. And is that one of the documents --
MR. SLATER: Objection.
BY MR. COMBS:
Q. -- that you relied upon in forming your opinions in this case?
A. Yes.
MR. SLATER: Objection.
BY MR. COMBS:
Q. Dr. Elser, have you reviewed the specific warnings that Dr. DeHasse gave Mrs. Bellew in this case?
A. Yes, I have.
Q. And what did those warnings indicate to you that Dr. DeHasse understood about this procedure?
A. I believe she talked about pain, scarring and dyspareunia as risk factors.
Q. And what did you take from that?
A. That Dr. DeHasse was aware that these could be the outcome after a vaginal prolapse procedure using mesh.
Q. And as you testified earlier, those would be facts that any pelvic floor reconstructive surgeon would know, aren't they?
A. Yes.

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MR. SLATER: Objection.
BY MR. COMBS:
Q. Dr. Elser, Mr. Slater asked you questions about long-term pain after Prolift. Do you remember those questions?
A. Yes, I do.
Q. I want to ask you some questions about contraction at the mesh arms which Mr. Slater asked you about. Have you ever experienced this in any of your patients?
A. Yes, I have.
Q. And was that a risk that you were aware of before implanting the Prolift device?
A. Yes.
MR. SLATER: Objection.
BY MR. COMBS:
Q. How did you know that?
A. We talked about it at the initial training. It was talked about not to place the mesh under excessive tension, which is also included in the monograph, to avoid tension on the mesh arms and help avoid contraction, pain at the contraction site.
Q. And can you explain briefly how placing the mesh with improper tension would increase the

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risk of contraction at the mesh arm?
MR. SLATER: Objection.
BY THE WITNESS:
A. The mesh is placed typically with a patient under general anesthetic and in a supine position so we know that even immediately when that patient wakes up and stands up, no longer has muscle relaxant in her system and she now stands up and puts pressure on her pelvic floor, that there is immediately going to be some uptake, some increase in tension on the mesh that's placed.
That's even before she starts having more daily activities of lifting, exercise, intercourse, bowel movements. So, it has to be placed without tension, in fact, with a little laxity to it, to allow for that change.
Q. Did Dr. DeHasse testify in her deposition that she in fact did place the mesh under tension?
MR. SLATER: Objection.
BY THE WITNESS:
A. She describes pulling the mesh arms until the mesh laid flat. And I was taught initially and I always taught that you want to leave it kind of like your teenager would throw

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their comforter on a bed, really loose with lots of ripples on it.
BY MR. COMBS:
Q. When you have had patients in your practice that have had contraction at the mesh arm, how have you treated those?
A. So, patients with contraction at the mesh arm, first of all, we want to distinguish is it symptomatic or not. If it's something I find on exam but the patient has no pain, it's not necessarily going to require treatment.
If it's causing problems for the patient, however, because the mesh arm is connected to the obturator which is connected to pelvic muscles, I want to check for pelvic floor tension, myofascial problems and then if we can get those muscles to relax, that may ease up all the tension and a mesh band may no longer be felt. So, it may not be just fibrosis and scarring. It may be tension from the muscles nearby pulling on it.
Q. And --
A. So, the first line is not surgical.
Q. And what are some of the alternative therapies that you would use?
A. So, therapies we'll use are pelvic floor

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physical therapy, use of muscle relaxants such as benzodiazepine like Valium and typically we'll advise patients to use that vaginally, not by mouth, so they don't have systemic side effects.
We may use a different type of antidepressant like amitriptyline, which helps with neuropathic myofascial pain.
And then direct injections into the muscle usually with a local anesthetic and perhaps a steroid but sometimes just dry needling those muscles will get them to relax.
Q. And have you reviewed Dr. Elliott's examination that he conducted in May of Mrs. Bellew?
A. Yes, I did.
Q. And at that time did Dr. Elliott find Mrs. -- strike that.
At that time did Mrs. Bellew relate complaints to Dr. Elliott related to the mesh arms?
A. No. He stated that she did not tolerate the exam well, that she had introital pain and winced and retracted from the examining finger. He had difficulty putting a speculum in from tightness at the introitus, which is not near the mesh arms.
He palpated along the left sulcus. He

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describes a tenderness along the left sulcus but that no mesh band is palpable in this area.
Q. Dr. Elser, I want to ask you some questions about Mrs. Bellew's clinical presentation. When -- strike that.
Mr. Slater asked you some questions about Mrs. Bellew's presentation and whether she exhibited pain. Did other records in addition to the one that Mr. Slater reviewed with you indicate that Mrs. Bellew did present with pain prior to the implant surgery?
MR. SLATER: Objection.
BY THE WITNESS:
A. Yes, there was a note from her primary care doctor, Dr. Leano, they had talked about she had been to the ER with abdominal and pelvic pain.
BY MR. COMBS:
Q. Now, Mr. Slater asked you questions about whether she showed signs of incontinence. Were there in fact other records that did indicate that she was exhibiting incontinence at the time of the Prolift implantation?
MR. SLATER: Objection, ambiguous.
BY THE WITNESS:
A. One of the notes before the surgery from

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the primary care doctor's office did state she had complained of leaking with cough and then Dr. DeHasse on the initial visit prescribed oxybutynin, which is an oral anticholinergic medication used to treat overactive bladder or urge incontinence.
BY MR. COMBS:
Q. And the indication for that medication would be from a patient suffering from urge incontinence?
MR. SLATER: Objection.
BY THE WITNESS:
A. Urge incontinence, frequency, nocturia.
BY MR. COMBS:
Q. Now, Mr. Slater asked you some questions regarding whether Mrs. Bellew suffered from pelvic floor muscle spasm. Do you remember those questions?
A. Yes.
Q. Now, did Dr. DeHasse evaluate Mrs. Bellew for pelvic floor muscle spasm prior to the implant?
A. I don't believe she evaluated it. If she did, it's not mentioned whether the muscles were normal tone, hypertonic, tender or not.

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Q. And so there is no record from Dr. DeHasse that she made that evaluation and ruled that out, is there?
A. No.
MR. SLATER: Objection.
BY MR. COMBS:
Q. Now, did Mrs. Bellew suffer from risk factors for pelvic floor muscle spasm?
A. Yes, she did.
Q. And what are those risk factors?
A. She suffered from chronic --
Q. Well, strike that.
I want to ask you now about risk factors that she presented with prior to the Prolift implant.
A. Okay.
Q. Did she suffer from risk factors prior to the Prolift implant?
A. Yes.
MR. SLATER: Objection.
BY THE WITNESS:
A. Primarily she had chronic pain that was myofascial which was related to her neck and back. She's using chronic narcotics for that. So, patients who have chronic myofascial pain in one

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area are more prone to be hypersensitive and develop myofascial pain in other parts of the body.
And in addition she's a smoker, and people who have a chronic cough from -- associated with smoking are putting pressure on their pelvic floor and they are more likely to have pelvic floor muscle tension.
Q. And she had in fact suffered from a prolapse, hadn't she?
A. Yes.
Q. And is that also an indication that she could have pelvic floor muscle issues?
A. Yes, it is. She has dysfunctional pelvic floor muscles.
Q. What did you take away from the fact that Mrs. Bellew presented to the ER with pain as a result of a grade 2 cystocele?
A. Having the primary presenting complaint --
MR. SLATER: Objection.
BY THE WITNESS:
A. -- for grade 2 cystocele is incredibly unusual. Usually patients with a cystocele sitting right at the introitus, which is what a grade 2 is, will present with, oh, a typical example is I took

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a shower today and I went to dry myself and I noticed something there that shouldn't be there. Then I looked in the mirror and I saw something.
But pain is not typically the presenting complaint with rare exceptions. Sometimes there is a very large grade 2 cystocele that's under high tension and feels like a water balloon that wants to burst. The ligaments and muscles are under so much tension from this impending further prolapse, but it's usually so -- such a dramatic finding that I would expect to hear something about that in the description of the exam.
Q. Now, these risk factors that Mrs. Bellew exhibited for pelvic floor muscle spasm prior to the Prolift implant, are those risk factors that you have seen other patients that you have treated clinically?
MR. SLATER: Objection.
BY THE WITNESS:
A. Yes. Oh, let me add to the risk factors. She is on narcotics. So, most of our patients on chronic narcotics are constipated and straining. It's not necessarily something that's routinely screened for in patients with prolapse but needs to be.

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BY MR. COMBS:
Q. And she also has presented with back pain, is that correct?
A. Yes.
MR. SLATER: Objection.
BY MR. COMBS:
Q. And is that also indicative -- or strike that.
Can back pain also be a potential cause of pelvic floor muscle spasm?
A. Absolutely.
MR. SLATER: Objection.
BY MR. COMBS:
Q. Why is that?
A. Our lower back muscles are connected to our pelvic muscles and tension in one may cause tension in the other or the back pain may be resulting from a disk problem, spinal stenosis, and those nerves are going to affect the pelvic floor muscle tone.
Q. And these opinions that you have regarding Ms. Bellew's risk factors for pelvic floor muscle spasm, what are they based on?
A. They are based on clinical experience, but there is also literature dating back as early

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as 2005 in the Ob-Gyn general literature describing the importance of evaluation of muscle tone in patients with prolapse both to see if they have weak muscles and could use some pelvic muscle strengthening exercises or to see if they have chronic constipation and pelvic floor muscle spasm and need down training.
Q. And you have treated other patients that have presented with these same or similar symptoms.
A. Yes.
Q. And have those other patients also exhibited pelvic floor muscle spasm?
A. Yes.
Q. And is that the basis for your finding that Mrs. Bellew could have been suffering from pelvic floor muscle spasm prior to the Prolift surgery?
A. Yes.
MR. SLATER: Objection.
BY MR. COMBS:
Q. Are there any other bases for that finding?
A. No. It's experience. Pelvic pain is frequently the cause especially when the degree of cystocele cannot explain the symptoms.

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Q. Now, Dr. Elser, did Mrs. Bellew have a concomitant vaginal procedure of a hysterectomy at the same time that she had the Prolift implant?
MR. SLATER: Objection.
BY THE WITNESS:
A. Yes, she did.
BY MR. COMBS:
Q. And what risks were presented by that vaginal hysterectomy?
A. Having a hysterectomy at the same time increases the risk of granulation tissue and mesh erosion exposure.
Q. And did that vaginal hysterectomy also independently present the risk of -- the risks that you have talked about here today regarding pelvic floor surgeries?
MR. SLATER: Objection.
BY THE WITNESS:
A. Patients undergoing a simple vaginal hysterectomy can have dyspareunia and myofascial pain after.
BY MR. SLATER:
Q. And is it your belief that Mrs. Bellew -- Ms. Bellew's hysterectomy would be a contributing cause of the pelvic floor -- strike

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that.
Is it your belief that Mrs. Bellew's vaginal hysterectomy would be a contributing cause of any pain that she is suffering now?
MR. SLATER: Objection.
BY THE WITNESS:
A. It could be.
BY MR. COMBS:
Q. Dr. Elser, what do you believe is causing the pain that Mrs. Bellew claims to currently experience?
A. Well, based on Dr. Elliott's exam, which is the last pelvic exam of record we have, she no longer had pain at the mesh site that had been excised. That mesh tension was relieved. There was some tenderness along the sulcus. But if there's also myofascial tenderness, which there was on this exam, and that's untreated, it's impossible to say if that sulcus pain would be there once the muscle pain was resolved because it likely would be.
If we take the pressure off that sulcus, by letting the muscles soften, have less spasm, the pain may very well be resolved and find there that is no residual scar causing a problem.

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Q. Now, Mr. Slater asked you a number of questions about whether surgeries can cause permanent myofascial pain. Do you remember those questions?
A. Yes.
Q. Now, do surgeries of the type that Mrs. Bellew had raise the risk of permanent myofascial pain?
MR. SLATER: Objection.
BY THE WITNESS:
A. Once she had the contraction band at the mesh arm identified and that was surgically excised, that surgical excision was a minor procedure. Yes, she did have three of them, but each time it was an incision over the scar band. The mesh was dissected out and removed where it was palpated to be in a scar band. That in and of itself would be more likely to relieve the myofascial tension than to cause it.
BY MR. COMBS:
Q. And that would not be more likely than not to be a cause of permanent myofascial pain in Mrs. Bellew's pelvic floor, would it?
A. Correct.
MR. SLATER: Objection.

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BY MR. COMBS:
Q. Dr. Elser, have you reached opinions regarding Mrs. Bellew's preexisting disability?
A. As far as we can tell from the records and her -- her testimony, she was declared disabled after her neck injury and her cervical spine surgery.
Q. And those are set forth in your report?
A. Yes.
Q. Dr. Elser, Mr. Slater asked you some questions about trocar passage. Do you remember those questions?
A. Yes.
Q. Do pelvic floor surgeons use other procedures and devices that involve trocars?
A. Yes.
MR. SLATER: Objection.
BY THE WITNESS:
A. We have performed traditional slings and needle suspensions using trocars that are passed through small incisions through the pelvis.
BY MR. COMBS:
Q. And how long have pelvic floor surgeons been using devices that involve trocars?
A. Decades.

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Q. And does the use of a trocar make a procedure unsafe?
A. No. One has to know the anatomy where the trocar is being placed and how to pass it in the safest way possible.
MR. SLATER: I just want to interject. It's five of. You have got -- you have left me a lot of stuff to cover. I just want to let you know that.
MR. COMBS: Okay.
BY MR. COMBS:
Q. Mr. Slater asked you questions regarding your use of Prolift. At the time the Prolift was decommercialized, were you still using it?
A. Yes. I had in fact a few cases scheduled the week that it was announced that it was no longer being supported and so made a decision to change those patients to other procedures.
Q. So, at that time it was still a procedure that you were offering to your patients and using in your patients?
A. Yes.
MR. SLATER: Objection. Leading.
BY MR. COMBS:
Q. Dr. Elser, the risks that you have

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discussed related to Prolift, with the exception of exposure, are those risks that are present with all pelvic floor surgeries?
MR. SLATER: Objection.
BY THE WITNESS:
A. Exposure and then the specific tenderness at the mesh arms is a risk unique to Prolift as opposed to mesh that does not have arms.
BY MR. COMBS:
Q. And Mrs. Bellew did not have an exposure or erosion, did she?
A. No.
Q. And the risks that you've discussed of potential scarring, is that also a risk that is equally presented with native tissue repairs?
A. Patients --
MR. SLATER: Objection.
BY THE WITNESS:
A. Patients undergoing any prolapse surgery can have scarring and pain.
BY MR. COMBS:
Q. Including abdominal sacrocolpopexy?
A. Yes.
MR. SLATER: Objection.
MR. COMBS: Let's take a break for a minute,

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Adam. I'm going to see if I have anything else and then you can do your redirect.
MR. SLATER: You asked a lot of questions and I need to finish today.
MR. COMBS: Okay. Thank you.
THE VIDEOGRAPHER: The time is 3:57 p.m. This is the end of Tape 2 and we are going off the video record.
(WHEREUPON, a recess was had from 3:52 to 4:02 p.m.)
THE VIDEOGRAPHER: The time is 4:02 p.m. This is the beginning of Tape 3 and we are back on the video record.
MR. COMBS: Adam, that's all the questions I have for Dr. Elser at this time. I might have some follow-up after you're done.
MR. SLATER: Splendid. Okay.
Dr. Elser -- are we back on, by the way?
MR. COMBS: Yes.
THE WITNESS: We're on.
FURTHER EXAMINATION
BY MR. SLATER:
Q. Dr. Elser, the version of the IFU you have in front of you, do you know when that IFU was in effect?

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A. The date on it says 11/07.
Q. Does that mean anything to you in terms of when it was in effect? Do you know the point in time when it went into use and when it went out of use?
A. No, I don't.
Q. Do you know whether you ever saw that IFU before you were retained to look at it in this litigation?
A. I don't know and I thought about this earlier. When you initially learn a procedure, you get the IFU and you look at it, you examine it and you may pull it out if you haven't done the procedure in a while.
But I can't say how a surgeon would ever know once an IFU changes to think to look for a newer version if they're still doing the procedure. So, that's one reason we would not look to the IFU for updated list of complications.
Q. Are you aware of the fact that a medical device company can tell the doctors that they are working with that the IFU has been updated and suggest that they take a look at the parts that have been updated?
A. Oh, absolutely.

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Q. You said that one of your bases for your opinions about the IFU is based on speaking to doctors about the IFU. Remember you said that?
A. Yes.
Q. Can you tell me who you spoke to and when you spoke to them and what -- so that I know what you're relying on?
A. Well, it was mostly when we did cadaver courses and preceptor courses and the physicians would always have a lot of questions for us in between or after or at the cadavers. We would talk about what was in the IFU or what points were important and --
Q. Nothing that I could be able to -- nothing you could tell me so I could verify who you spoke to and when you spoke to them and what the content was, right?
A. No.
Q. And, of course, you don't know what was in their minds beyond what you discussed. So, for example, a doctor may have asked you questions about the procedure and you may have discussed the IFU in that context and the doctor could have on his or her own read all of the warnings and adverse events and relied on that without discussing that

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with you. That could have happened many times, right?
A. That could have.
Q. The IFU does not say anything about the level of knowledge a surgeon would need to have or be expected to have regarding the Prolift procedure. It doesn't say that, right?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. It says they should be familiar with pelvic reconstructive surgery and placement of non-absorbable mesh.
BY MR. SLATER:
Q. And how is "familiar with" defined in the IFU? Is there any definition offered there?
A. Not that I saw.
Q. In fact, some doctors could think that if they had done three procedures with mesh where they sewed it in as part of a colporrhaphy that they were familiar with mesh procedures, right?
A. Oh, yes. There is a lot left up to surgeon judgment.
Q. So, "familiar with" really is a word that doesn't really mean anything unless you ask the person who is reading it what they think it

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means, right?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. It's up to the surgeon to know if they have sufficient knowledge of a new procedure to undertake it in a patient.
BY MR. SLATER:
Q. And sufficient knowledge, that's not something that could be defined in any objective way, right?
A. Right.
Q. There is nowhere in the IFU where it's disclosed that Prolift complications could lead to multiple operations and despite the multiple operations, the woman would not get better and could actually be left with permanent disabling pain, those words and words to that effect do not appear in the IFU, correct?
A. I did not see that in the IFU.
Q. That is a risk with the Prolift, correct?
A. It's a risk with the Prolift and with other pelvic surgeries.
MR. SLATER: Move to strike from "and" forward.

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BY MR. SLATER:
Q. Did Ms. Bellew's records indicate that she had a chronic cough?
A. No. I'm surmising that she's likely to have a chronic cough since she is a smoker and she has lung disease and has been placed on oxygen.
Q. You're speculating that Ms. Bellew had a chronic cough, correct?
A. Yes, because I take care of a lot of smokers.
MR. SLATER: Move to strike after "yes."
BY MR. SLATER:
Q. In terms of your testimony about whether or not Ms. Bellew had pelvic floor myalgia before the Prolift surgery, first of all, there is no medical record documenting that that condition existed, correct?
A. Correct.
Q. You're speculating that it may have existed but you have no proof, correct?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. I'm speculating that it was likely to have been there, yes.
BY MR. SLATER:

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Q. Well, in terms of your opinions about whether or not Ms. Bellew had pelvic floor myalgia before the Prolift surgery, there is no objective evidence in any medical record indicating that, correct?
A. Correct.
Q. I'm correct, right?
A. Yes. Oh, I said yes. Sorry.
Q. So, any opinion you would offer that Ms. Bellew had pelvic floor myalgia before the Prolift surgery would be speculative since there is no objective evidence of it, correct?
A. Yes.
Q. You talked about the hysterectomy a little bit.
A. Yes.
Q. I don't need to ask about that. Let's see what else I can do.
Did you see pictures that were taken of any of the mesh that was removed from Ms. Bellew's body?
A. No.
Q. You did not see any of the expert reports with regard to the pathology?
A. No.

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Q. And the pathologic analysis of the removed mesh or tissue, right?
A. Correct.
Q. Whatever Ms. Bellew's condition was before the Prolift and whatever other conditions she may have had, that did not impact on the fact that she ended up with mesh contraction, hardened mesh, pain from that hardened mesh, dyspareunia from that hardened mesh and the need for three operations to remove that mesh, correct?
MR. COMBS: Object to the form.
BY THE WITNESS:
A. Potentially. So, because I'm making the assumption that she likely had myofascial hypertonicity, that can cause a tight mesh band that may not be true hardening like a calcification of the mesh but tension on the mesh arm that would be tender to palpation.
Q. If she had myofascial pain before the Prolift, that would be a contributing factor; but the Prolift itself being in the body and its interaction with the body would be the primary cause of those conditions and those problems, right?
A. Well, again, if I could explain a little

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further. If you palpate a mesh arm and it feels taut, you can say there's fibrosis contraction of tissue grown around the mesh arm or that the muscle that's attached at the end of the mesh is tight and pulling on the mesh arm to make it feel tight on exam and if I relieve that tension or cut the arm, I'm just breaking that cycle. They are no longer connected.

So, yes, she had tension where the mesh arm was; but if the muscle was of normal tone, it might no longer feel hard and taut.

Q. Well, in this case Dr. DeHasse actually confirmed that she looked at the mesh and could see that there was fibrotic scar plates actually on the mesh and contracting the mesh, correct?

MR. COMBS: Object to the form.

BY MR. SLATER:

Q. She confirmed she observed that, correct?

A. Yes, but as a surgeon who has taken out mesh arms, I don't know what that means.

Q. Well, assuming Dr. DeHasse saw the fibrotic tissue encrusted across the mesh, that's -- you have no reason to dispute that, do you?

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MR. COMBS: Object to form.

BY THE WITNESS:

A. Well, there's scar tissue that's laid down, fibrosis that may not be under undue tension that wouldn't necessarily be painful to the patient.

So, I'm saying it's the combination of the mesh band being there and tension that may be causing the pain and tension she is feeling.

BY MR. SLATER:

Q. You have no evidence from any medical record or document that there was pelvic floor myalgia causing a tension band before the Prolift was put in or during the time when it was being treated by Dr. DeHasse, correct?

A. Correct.

MR. SLATER: I have no other questions.

MR. COMBS: Very, very brief.

FURTHER EXAMINATION

BY MR. COMBS:

Q. Dr. Elser, Mr. Slater asked you about a risk of multiple operations to treat complications from Prolift. In fact, the risk of multiple operations to treat complications would be a risk of any pelvic floor surgery, wouldn't it?

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MR. SLATER: Objection.

BY THE WITNESS:

A. Yes.

BY MR. COMBS:

Q. Mr. Slater asked you about no objective evidence in any medical record of the fact that Ms. Bellew had pelvic floor myalgia prior to the Prolift implant. But in fact there would be objective evidence of all the risk factors that you described related to the potential for her having pelvic floor myalgia, isn't there?

A. Yes.

MR. SLATER: Objection.

MR. COMBS: That's all the questions I have, Adam. Anything else?

MR. SLATER: Nope.

MR. COMBS: Okay.

MR. SLATER: See you at the next one, Dr. Elser.

THE VIDEOGRAPHER: Okay. The time is 4:12 p.m. This is the end of Tape 3 and it also concludes the deposition of Dr. Denise Elser and we are off video record.

(Time Noted: 4:12 p.m.)

FURTHER DEPONENT SAITH NAUGHT.

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I, CORINNE T. MARUT, C.S.R. No. 84-1968, Registered Professional Reporter and Certified Shorthand Reporter, do hereby certify:

That previous to the commencement of the examination of the witness, the witness was duly sworn to testify the whole truth concerning the matters herein;

That the foregoing deposition transcript was reported stenographically by me, was thereafter reduced to typewriting under my personal direction and constitutes a true record of the testimony given and the proceedings had;

That the said deposition was taken before me at the time and place specified;

That the reading and signing by the witness of the deposition transcript was agreed upon as stated herein;

That I am not a relative or employee or attorney or counsel, nor a relative or employee of such attorney or counsel for any of the parties hereto, nor interested directly or indirectly in the outcome of this action.

It was requested before completion of the deposition that the witness, DENISE M. ELSER, M.D., have the opportunity to read and sign the deposition transcript.

_____

CORINNE T. MARUT, Certified Reporter

(The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)

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After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

DENISE M. ELSER, M.D. DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

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Notary Public

LAWYER'S NOTES

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